
CMS Manual System

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Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 13

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SUBJECT: Revisions to Chapter 2, “The Certification Process,” Appendix E-- “Providers of Outpatient Physical Therapy or Outpatient Speech Language Pathology (OPT/OSP) Services,” and Appendix K-- “Comprehensive Outpatient Rehabilitation Facilities”

I. SUMMARY OF CHANGES: The purpose of this revision to Chapter 2, Appendix E, and Appendix K is to delete material, provide clarifying instructions and surveyor guidance for regulations, add deficiency tags, and regulation language to the Appendices. In addition, Sections 2292B and C were combined under Section 2292B in Chapter 2.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: November 21, 2005
IMPLEMENTATION DATE: November 21, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	2/Table of Contents
R	2/2292/Types of OPT/OSP Providers
R	2/2292A/Rehabilitation Agency
R	2/2292B/Clinics and Public Health Agencies
R	2/2298/Sites of Service Provision
R	2/2298A/OPT/OSP Services Provided at More Than One Location
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R	2/2300/SA Annual Report to RO on Locations of Extension Locations
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R	2/2362/Scope and Site of Services
R	2/2364A/Shared Space With Another Provider or Supplier
R	2/2364B/Sharing of Equipment
R	Appendix K/§485.54/Condition of Participation: Compliance With State and Local Laws/

R	Appendix K/§485.56/Condition of Participation: Governing Body and Administration
R	Appendix K/§485.58/Condition of Participation: Comprehensive Rehabilitation Program
R	Appendix K/§485.60/Condition of Participation: Clinical Records
R	Appendix K/§485.62/Condition of Participation: Physical Environment
R	Appendix K/§485.64/Condition of Participation: Disaster Procedures
R	Appendix K/§485.66/Condition of Participation: Utilization Review Plan
R	Appendix E/§485.707/Condition of Participation: Compliance with Federal, State and Local Laws
R	Appendix E/§485.709/Condition of Participation: Administrative Management
R	Appendix E/§485.711/Condition of Participation: Plan of Care and Physician Involvement
R	Appendix E/§485.713/Condition of Participation: Physical Therapy Services
R	Appendix E/§485.715/Condition of Participation: Speech Pathology Services
R	Appendix E/§485.717/Condition of Participation: Rehabilitation Program
R	Appendix E/§485.719/Condition of Participation: Arrangements for Physical Therapy and Speech Pathology Services to be Performed by Other Than Salaried Rehabilitation Agency Personnel
R	Appendix E/§485.721/Condition of Participation: Clinical Records
R	Appendix E/§485.723/Condition of Participation: Physical Environment
R	Appendix E/§485.725/Condition of Participation: Infection Control
R	Appendix E/§485.727/Condition of Participation: Disaster Preparedness
R	Appendix E/§485.729/Condition of Participation: Program Evaluation

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

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Chapter 2 - The Certification Process

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*2298B – OPT/OSP Services at Locations Other than Extension
Locations*

2302 – Survey of OPT/OSP Extension Locations

Chapter 2

Providers of Outpatient Physical Therapy or Outpatient Speech Pathology (OPT/OSP) Services

2292 - Types of OPT/OSP Providers

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

There are three types of organizations that may qualify as OPT/OSP providers. *However, almost all OPT/OSP providers are rehabilitation agencies.*

2292A - Rehabilitation Agency

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

An agency that provides an integrated, multidisciplinary program designed to upgrade the physical functions of handicapped, disabled individuals by bringing together, as a team, specialized rehabilitation personnel. At a **minimum**, a rehabilitation agency must provide physical therapy or speech language pathology services **and** a rehabilitation program that, in addition to physical therapy or speech language pathology services, **includes social or vocational adjustment services**. *The organization must have two persons on duty on the premises of the organization whenever a patient is being treated whether at the primary site or the extension locations.*

NOTE: Occupational Therapy cannot be substituted for the physical therapy requirement. It may be provided in addition to physical therapy or speech-language pathology services.

The organization has available a physician on call to furnish necessary medical care in case of an emergency.

2292B – Clinics and Public Health Agencies

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

On rare occasions, a facility established primarily for the provision of outpatient physicians' services or an official agency established by a State or local government, the primary function of which is to maintain the health of the population served by providing environmental health services, preventive medical services, may in certain instances provide therapeutic services. Those entities will want to contact their Fiscal Intermediaries/Carriers regarding the provision of OPT/OSP services. Definitions for clinics and public health agencies may be found at 42 CFR §485.703.

2298 - Sites of Service Provision

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

An OPT/OSP provider (normally classified as a rehabilitation agency) furnishes services at its primary (that has an approved Medicare Provider number) site.

2298A - OPT/OSP Services Provided at More Than One Location

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

An OPT/OSP provider may also provide services from locations other than its primary site. These locations may be freestanding offices, suites in an office or medical building or, in some cases, space in an existing Medicare/non-Medicare participating provider (SNF or hospital) and are called extension locations.

The extension location concept for OPT/OSP is applicable only in those cases in which a separate area of a host provider or facility is set aside for the provision of OPT/OSP services during the hours of the OPT's operations. (An example—SNF patients may not be treated in the OPT area during the OPT's hours of operation). The extension location must meet all applicable CoPs (refer to §2302). The OPT should have established policies and procedures related to service provision at the extension location. Medical records for patients treated at the extension locations must be readily available for surveyors during surveys.

The extension location cannot provide services that the primary location is not providing (with the exception of aquatic therapy). Extension locations do not have to provide all the services that are provided at the primary site. For example, an extension location may provide occupational therapy services as long as the occupational therapy services are being provided at the primary location. Alternatively, physical therapy may be provided at the primary location but does not have to be provided at the extension location.

NOTE: *The OPT/OSP primary site must provide the therapeutic services that are provided at the extension locations. The OPT/OSP may provide a therapeutic service directly at one location while providing it under arrangement at another. A therapeutic service refers to a type of professional discipline (i.e., physical therapy, occupational therapy, social services, etc). Therapeutic services do not refer to particular types of treatment modalities (such as ultrasound or other types of physical agents) applied to produce therapeutic changes to biologic tissue. The primary site and the extension locations do not have to provide the same types of modalities. However, the primary site and the extension locations must have the appropriate modalities to treat the types of diagnoses/dysfunctions of the patients each serves.*

As long as an OPT/OSP is not operating in the same space at the same time, there appears no reason why the OPT/OSP cannot operate on the premises of a supplier (i.e., physician, chiropractor). However, the supplier cannot bill separately for the services provided by the OPT/OSP and the supplier must adhere to sections of the Social Security Act that prohibit suppliers from referring Medicare patients for certain designated health services (DHS) to an entity with which the supplier or a member of the supplier's immediate family has a financial relationship, unless an exception applies. The OPT has the responsibility to protect the medical records from unauthorized use.

2298B - OPT/OSP Services at Locations Other than Extension Locations

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The OPT/OSP may provide therapy services in the patient's home or in a patient's room in a SNF. Because they are not considered extension locations, neither the home nor a patient's room need satisfy the requirements for an extension location.

Periodically, an OPT/OSP may wish to use a community facility to provide certain therapy services. For example, the OPT/OSP provider may want to use a community pool to provide aquatic therapy. The State agency (SA) shall verify that the community pool meets all applicable state laws (i.e., health and safety, infection control requirements, etc.) governing the use of the community facility. Also the SA shall review the OPT/OSP's policies and procedures regarding the type of therapy being provided, training for staff, supervision, etc. The pool must be closed to public use during the time the OPT/OSP is providing therapy to protect the privacy and safety of the patients being treated. The hours of operation and days of the week during which the facility will be used for therapy services, supervision, etc. must be clearly stated in the OPT/OSP's policies and procedures as well as the contractual agreement between the community pool and the OPT/OSP. Verify that the OPT/OSP has a carefully detailed policy regarding specific arrangements for emergency services in the event that a medical emergency were to occur at the community location (i.e., is a telephone in close proximity to the qualified professional providing the service, is there a second person on site? etc.)

The SA shall survey the site to determine if the location meets the State's health and safety standards. The SA should consult with their RO regarding their reasons and decision to accept or deny the community facility. The community facility would not be considered an extension location.

2300 - SA Annual Report to RO on Locations of Extensions Locations

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

OPT/OSP providers are required to report the proposed addition of all new extension locations. In addition, on an annual basis or on or before January 1 of the calendar year,

the SA forwards a copy of the Identification of Extension Locations of OPT/OSP Providers (Form CMS-381) to all OPT/OSP providers. If possible, the SA should complete this activity within the same time period for all OPT/OSP providers. Each provider providing services from extension locations is to indicate, in the appropriate spaces, the name, address and the provider number of the primary site, as well as the name(s) and address(es) of extension location(s) and, under Part B, the specific services (OPT, OSP, or both) each extension location provides. Upon receipt of this form from the OPT/OSP provider, the SA reviews this information, identifies those locations requiring a survey and schedules the survey accordingly.

NOTE: The SA forwards an annual summary report of the information to the RO noting the number of extension locations for each certified OPT/OSP provider. *After reviewing the forwarded reports, the RO & SA may wish to mutually identify any required surveys.*

NOTE: ROs are responsible for entering OPT/OSP extension locations identifiers (similar to HHA branches) into ASPEN. The identifiers can be included in the survey process.

2302 – Survey of OPT/OSP Extension Locations

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The extension location must meet all applicable CoPs. The SA may survey as many facility locations as it deems necessary to adequately determine the rehabilitation (OPT/OSP's) agency's overall compliance with the OPT/OSP CoPs.

The SA surveys each condition and standard in the OPT/OSP CoPs at each extension location with the following exceptions:

- 42 CFR 485.709(a) (Standard: Governing body) is based upon the evaluation of the total agency that has responsibility for the primary location as well as all extension locations. *However, if there are concerns with the day-to-day operations of the extension location, assess the effectiveness of the governing body.*
- Condition 485.717 (Rehabilitation program) is applicable only to a rehabilitation agency's own patients;
- Condition 485.715 (Speech pathology) is applicable only when speech pathology is rendered.
- *Condition 485.713 (Physical therapy services) is applicable only when physical therapy is rendered*

The SA completes a separate survey report, Form CMS-1893, for each surveyed OPT location. Failure to correct deficiencies noted as a result of a survey at any location (extension location or primary site) will jeopardize the certification of the OPT provider in its entirety. The SA completes only one Form CMS-2567, and indicates the names of all locations (primary and/or extension location) found to be deficient with respect to each survey item. Also, the SA completes only one Form CMS-1539, and notes the names of all facilities that serve as extension locations in "State Agency Remarks." Surveys of all locations must be coordinated; therefore, schedule and complete surveys of all locations within the same time period.

When the SA is certifying compliance, findings at all locations are to be considered as a whole. If the OPT provider has deficiencies in only some locations, but they are judged significant enough to warrant termination, the SA initiates termination proceedings. Cessation of services at the location(s) at which the deficiency(ies) existed, in lieu of initiating corrective action, would enable the OPT provider to retain its certification.

NOTE: For an OPT/OSP provider to establish an extension location across the State lines, the two States involved must have a signed reciprocal agreement with each other allowing approval of the extension location. Whether the extension location is in the same State as the primary site or in another State, it must conform to all regulatory requirements. An extension location that is situated in a different State should bill under the primary site's provider number.

An extension location cannot be denied based solely on geographical distance. If there is considerable geographical distance between the primary site and the extension location(s), it is important to determine whether the primary site can adequately supervise the staff at the extension location(s) as well as manage and oversee all operations of the extension location. Supervisors should be available by telephone and be able to drive to the extension location in a reasonable amount of time, provide ongoing staff training, etc.

NOTE: A physical therapist may not supervise an occupational therapy assistant nor may an occupational therapist supervise a physical therapy assistant. Non-professional personnel (generally physical and occupational therapy aides) cannot be supervised by anyone other than the qualified physical or occupational therapist while performing patient care activities.

Chapter 2

Comprehensive Outpatient Rehabilitation Facilities (CORFs)

2362 - Scope and Site of Services

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The CORF provides a broad array of services that must include, at a minimum, the following three core services: physician services, physical therapy services and social work or psychological services.

With the exception of physical therapy, occupational therapy, and speech-language pathology services, all CORF services must be provided on the CORF premises. However, one visit to the patient's home is allowed to evaluate the home environment in relation to the patient's established treatment plan. Physical therapy, occupational therapy, and speech pathology services may be provided off the CORF premises (including a patient's home). ***The CORF is responsible for the implementation and supervision of any therapy services that are provided at an off-site location. All appropriate CoPs apply to the services provided at off-site locations.***

Covered CORF services are those that would be covered as inpatient hospital services if furnished in a hospital. Covered items or services must be reasonable and medically necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. A service furnished as part of a maintenance program involving repetitive activities not requiring the skilled services of nurses or therapists would not be covered. ***A CORF may be reimbursed for optional CORF services if they are part of a comprehensive, coordinated, skilled rehabilitation program. (Optional CORF services are: Occupational therapy, speech-language pathology, respiratory therapy, prosthetic and orthotic devices, nursing, drugs and biologicals, DME and a single home visit).***

2364A - Shared Space With Another Provider or Supplier

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A CORF may be established on the premises of another health entity even though the other entity is currently approved under Medicare as a provider or supplier of services. For example, a SNF owner may rent space within the SNF to the CORF. The CORF must be functionally and operationally independent from the SNF (see [§2360](#)).

A CORF may not share a common space with the other entity unless the CORF is able to fully function without interruption during its scheduled hours of operation. Use of the CORF space by another, or host entity, during CORF hours of operation is not allowed. For example, one room in a suite used by an OPT/OSP provider and owned by the OPT/OSP

provider or another party may function as a CORF location. However, although the CORF is located on the premises of the OPT/OSP provider, this space is not to be used for OPT/OSP purposes during the operating hours of the CORF. *The CORF must make provisions to secure medical records from unauthorized use.*

2364B - Sharing of Equipment

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Equipment may be shared in the same manner as space. All common equipment must be available on the premises of the CORF during hours of operation and not used at the same time by the other entity for any purpose.

A CORF need not own all of the equipment required for implementing a plan of treatment, but it must demonstrate that all required equipment can be readily procured when needed *and be available in the facility when providing treatment services to the patients.*

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Appendix E - Guidance to Surveyors: Outpatient Physical Therapy or Speech Pathology Services

(Rev. 13, 10-21-05)

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General Note: Extension Locations

§485.707 Condition of *Participation*: Compliance With Federal, State and Local Laws

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The organization and its staff are in compliance with all applicable Federal, State and local laws and regulations.

A - General

In order to assure that the clinic, rehabilitation agency, or public health agency and staff are in possession of current licenses as required by Federal, State and local laws, licenses should be available for review. Compliance with this Condition may have a direct bearing on other Conditions; e.g., physical therapy services (§[485.713](#)), speech pathology services (§[485.715](#)), rehabilitation program (§[485.717](#)), and physical environment (§[485.723](#)).

Review the licenses to assure the licenses are current and are applicable to the State in which the provider is providing services.

B - Major Sources of Information:

- Federal, State and local laws governing health care; building, fire and safety codes;
- Applicable State and local licenses and organization personnel records containing up-to-date information; and
- Written policies pertaining to communicable and reportable diseases, conforming to applicable Federal, State and local laws.

C - Standards

§485.707(a) Standard: Licensure of Organization

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

In any State in which State or applicable local law provides for the licensing of organizations, a clinic, rehabilitation agency or public health agency is licensed in accordance with applicable laws.

Where State law provides for the licensing of clinics, rehabilitation agencies or public health agencies, *the organization must meet all building, fire and safety codes, where required for licensure, before the organization is eligible for certification.*

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Verify* at the time of the survey that a current license is valid and in effect. A license must be in effect before the organization can be certified to participate in the program. Where a license for an organization currently participating has been temporarily suspended or revoked, contact the appropriate State department or authority to ascertain the status of the organization's licensure. If a license is not to be issued, *the facility should be found in noncompliance with this standard and termination proceedings initiated.

Some States may issue provisional licenses. Contact the appropriate State department or authority and obtain information concerning the length of time the provisional status is to be in effect. If the limitations stipulated in a provisional license adversely affect the ability to render services in compliance with regulations, *the facility should be found in noncompliance with this standard.*

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Document the reason(s) for such status and, most importantly, any limitation(s) imposed on the services rendered as a result.

§485.707(b) Standard: Licensure or Registration of Personnel

Staff of the organization are licensed or registered in accordance with applicable laws.

Qualified personnel providing services at an OPT must be licensed, registered, or certified when licensure, registration or certification is applicable. This includes personnel providing services directly or under arrangement.

I-9

Review facility records, a central State listing, or other evidence of current licensure or registration of personnel, such as wallet size identification cards sometimes made available. Where personnel are required to be licensed but are not, notify the appropriate State licensing body. *If extension locations are located in other States, ensure that personnel who are providing services are licensed in the State in which the services are provided.*

§485.709 Condition of *Participation*: Administrative Management

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The governing body designates an administrator, and establishes administrative policies.

A – General

*The clinic or rehabilitation agency has a governing body responsible for developing, reviewing, and updating its administrative and clinical policies and procedures. The provision of adequate and effective services requires that the clinic or rehabilitation agency be responsive to internal and external needs and demands which may necessitate changes in program operation. *The governing body is responsible for designating an administrator.**

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Review documentation of governing body activities to assess the effectiveness of the governing body's management and operation of the rehabilitation agency or clinic.

B – Major Sources of Information

- Articles of incorporation, bylaws, policy statements, etc.;
- Minutes of governing body; staff and patient care policy committee meetings;
- Organizational chart showing administrative framework;
- Personnel records—employee qualifications and licenses;
- Patient care policies; and
- Clinical records.

C – Standards

§485.709(a) Standard: Governing Body

There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State Agency. In the case of corporations, the names of the corporate officers are made known.

The governing body is the board of directors or trustees of a corporation, the owner(s) in the case of a proprietary clinic or rehabilitation agency, or others who have legal responsibility for the operation of the clinic or rehabilitation agency. The facility shall have an established and functioning governing body. It is not inappropriate for employees of an incorporated clinic or rehabilitation agency to also serve as members of the governing body. The governing body shall be responsible for compliance with all applicable laws and regulations pertaining to OPT/SLP facilities. The governing body is responsible for the quality and appropriateness of care. *Written* provisions should appear in the bylaws or equivalent, specifying:

- The basis upon which members of the governing body are selected (where applicable), their terms of office, and their duties and responsibilities;
- To whom responsibilities for direction of the program and evaluation of practices may be delegated, and the methods established by the governing body for holding appropriate individuals responsible; and
- The frequency of governing body meetings and that minutes are kept.

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

*Verify that the names and addresses of all individuals having legal responsibility for the clinic or rehabilitation agency are available on the provider's CMS-855A.
Verify that the Governing Body has by-laws, meetings and minutes of its meetings.
Verify that the organization has policies and procedures that address who monitors the quality of care provided and methods to evaluate the quality (QI) of the services.*

§485.709(b) Standard: Administrator

The governing body:

- (1) Appoints a qualified full time administrator;*
- (2) Delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies;*
- (3) Defines clearly the administrator's responsibilities for procurement and direction of personnel; and*
- (4) Designates a competent individual to act in the temporary absence of the administrator.*

***NOTE:** One qualified full-time administrator assumes overall administrative responsibility for the entirety of the rehabilitation agency's operation, including extension locations and any off-premises activities.*

The administrator who does not possess the required experience or specialized training in the administration of an outpatient physical therapy provider (rehabilitation agency, clinic, public health agency) may use training or experience acquired in the management or supervision of health institutions and agencies similar in scope to an outpatient physical therapy provider. College-level courses in health services administration and management approved by the appropriate State authority meet the necessary requirements for specialized training.

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(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Verify the qualifications of the administrator.

The administrator should be familiar with all aspects of the operation of the clinic or rehabilitation agency such as scope of services provided, budgetary and fiscal matters, personnel, and other areas necessary to effectively direct operational activities. The administrator is also responsible for coordinating staff education, sometimes referred to

as in-service education, or continuing education. In this regard, the administrator should see that each employee has the opportunity to increase the skills and knowledge necessary to promote effective and efficient patient care.

I-15

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review listing of in-service program content, type of instruction (e.g., lecture or demonstration), dates of instruction, and attendees.

When the administrator is unable to carry out delegated duties, a similarly qualified alternate is to be readily available (on the premises or by telephone) at all times during operating hours to assume the administrator's responsibilities.

I-15

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Verify that an *alternate to the administrator* has been selected *and is noted in organization policies*.

§485.709(c) Standard: Personnel Policies

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure if applicable.

At a minimum, facilities should have procedures for selecting qualified personnel; a system for documenting the current licensure and/or certification status for those personnel whose positions or functions require such licensure or certification; and a system for assessing competency of all personnel providing healthcare services, upon hire and on an ongoing basis, on a schedule determined by the facility policy. Practices pertaining to the personnel of the organization should be written in personnel policies, be available to all personnel, and be updated and/or revised as appropriate. Such items as qualifications of staff employed, frequency of supervision, continuing education, hiring/firing practices, evaluations, etc. should be located in the personnel policies.

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(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review *personnel* policies. During interviews with the facility administrator and staff, elicit evidence that personnel practices are based on written personnel policies.

§485.709(d) Standard: Patient Care Policies

Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient physical therapy and/or speech pathology services and related services that are provided. These policies are evaluated at least annually by the group of professional personnel, and revised as necessary based upon this evaluation.

The facility should have *written* patient care policies, *based on accepted standards of practice* for all services provided, *that govern the outpatient physical therapy and/or speech pathology services and related services that are provided. Patient care policies are established by the professional staff of the clinic or rehabilitation agency and, where appropriate, outside professionals who function as a patient care policy committee. The professional staff preparing the patient care policies should include at least one physician and at least one qualified physical therapist (if physical therapy services are provided) and at least one qualified speech pathologist (if speech pathology services are provided). Patient care policies should be reviewed for appropriateness at least annually by the group of professional personnel that prepared them.*

Review the written patient care policies and determine whether the facility operates in conformity with them.

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(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review minutes of meetings to determine whether the policies of the clinic or rehabilitation agency are current and responsive to the needs of patients, and whether, when unresponsive, appropriate policy revisions are undertaken. Verify that patient care policies are being reviewed annually and revised as needed.

§485.711 Condition of *Participation*: Plan of Care and Physician Involvement

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

For each patient in need of outpatient physical therapy or speech pathology services there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively. The organization has a physician available to furnish necessary medical care in case of emergency.

A - General

All patients must be treated pursuant to a written plan of care that indicates anticipated goals and specifies the type, amount, frequency, and duration of services to be furnished. Non-Medicare patients are neither required to be under the care of a physician nor to have a plan of care established by a physician. *A physician will be available on call to furnish necessary medical care in case of an emergency.*

I-47

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review medical records to ensure Medicare patients have a written plan of care.

B - Major Sources of Information

- Patients' plans of care;
- Emergency Procedures;
- Patient care policies; and
- Clinical records.

C – Standards

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

§485.711(a) Standard: Medical History and Prior Treatment

The following are obtained by the organization before or at the time of initiation of treatment:

- (1) The patient's significant past history;*
- (2) Current medical findings, if any;*
- (3) Diagnosis(es), if established;*
- (4) Physician's orders, if any;*

(5) Rehabilitation goals, if determined;

(6) Contraindications, if any;

(7) The extent to which the patient is aware of the diagnosis(es) and prognosis; and

(8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

The regulations do not require the patients be referred to be the facility by a physician or that the services to be furnished pursuant to a physician's orders. However, since Medicare patients are still required under the statute to be under the care of a physician and to have the plan of care periodically reviewed by a physician to receive payment for Medicare covered services, *the organization should, if possible, obtain the following information at, or prior to, the time that therapy is initiated: Significant past medical history, current medical findings, diagnosis(es), physician's orders (if any), rehabilitation goals and contraindications, (normally be made available to the facility by the attending physician) and any previous therapy or hospitalization related to the current medical condition.* Non-Medicare patients are not required to be under the care of a physician, *or to* have a plan of care established or periodically reviewed by a physician, *though* you should *nevertheless* expect to find medical records maintained for the *non*-Medicare patients. When complete and appropriate past history *and/or* current medical findings are not made available to the organization, the organization should obtain the information from *other sources such as* the patient, family or from follow-up with the referring physician, if any.

I-49

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review medical record for evidence of prior medical history and/or treatment.

§485.711(b) Standard: Plan of Care

- (1) For each patient there is a written plan of care established by the physician; or (i) by the physical therapist; or (ii) by the speech-language pathologist who furnishes the services.*
- (2) The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the—(i) type; (ii) amount; (iii) frequency; and (iv) duration.*
- (3) The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action taken. (For Medicare patients, the plan must*

be reviewed by a physician, nurse practitioner, clinical nurse specialist, or physician assistant at least every 30 days, in accordance with §410.61(e) of this chapter.)

- (4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.*

When you review a patient's record to determine if a plan of care has been established and is periodically reviewed, it is not necessary to establish whether the patient is a Medicare or non-Medicare patient. The condition statement and standard permit, for each patient, the plan of care to be established by a physician, or by the appropriate professional (i.e., a physical therapist or speech pathologist) and *to be* reviewed by a physician or the individual who established it. However, as a condition for Medicare payment, a physician must certify the necessity of the services. *As part of the certification, a* physician, nurse practitioner, clinical nurse specialist, or physician assistant must review the plan of care every 30 days. *For* each Medicare patient, *a physician must* re-certify the continued need for those services. This review will probably be the review the facility uses for Medicare patients to meet the Condition of Participation. Since Medicare patients must be under the care of a physician for purposes of receiving payment for Medicare covered services, the attending physician must be notified of any changes in current treatment or the patient's condition. A change requires a revision to the plan of care. The medical record should contain documentation regarding the notification (a dated written order signed by the physician or a dated verbal order signed by the professional receiving the order).

I-50

Review the medical record to determine that the patient has a plan of care that is being reviewed and updated every 30 days (for Medicare patients). The plan of care should not look identical from month to month as treatment and goals should be updated as the patient makes progress and meets existing goals. The plan of care must have the signature of the reviewing physician, non-physician practitioner, or therapist. If, for any reason, therapy services are discontinued prior to the end date indicated on the plan of care, the physician must be notified.

NOTE: The term physician includes a podiatrist *or optometrist* whose performance of functions are consistent with the OPT's *policies* and whose services are related to functions he/she is legally authorized to perform.

§485.711(c) Standard: Emergency Care

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The organization provides for one or more doctors of medicine or osteopathy to be available on call to furnish necessary medical care in the case of emergency. The established procedures to be followed by personnel in an emergency cover immediate care of the patient, persons to be notified, and reports to be prepared.

Organizational policies should contain the names and telephone numbers of physician(s) the organization has arranged to be on-call to provide medical care in case of an emergency during operating hours. (This can include physicians at a near-by hospital emergency room.) There may be instances in which the on-call physician provides emergency medical triage which results in a 911 call. The OPT procedure to call 911 in cases of emergency doesn't supersede the requirement to have on-call physicians for emergencies.

NOTE: *If an OPT/OSP is providing services at a community facility (such as a pool), the OPT staff must have a way to contact emergency medical care (i.e., if therapy services are being provided at a community pool, is another individual on duty and available to call for help?)*

I-54

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the medical emergency procedures, and make certain in discussions with the appropriate persons that these procedures, when necessary, can be made immediately operational. Interview employees to determine whether their individual responsibilities, in case of an emergency, are known. There must be two persons on duty whenever a patient is being treated (no matter where the services are being provided (§485.723(a)(6)) and no matter whether the facility is large or small.)

NOTE: *If a patient receives emergency medical treatment at the organization, the physician's emergency medical treatment plan and communication should be documented in the patient's medical record.*

§485.713 Condition of *Participation*: Physical Therapy Services

If the organization offers physical therapy services, it provides an adequate program of physical therapy, has an adequate number of qualified personnel, and the equipment necessary to carry out its program and to fulfill its objectives.

A - General

The range of medically necessary physical therapy services should be adequate to treat the types of disabilities accepted for service. There should be an adequate number of qualified professionals to accommodate the number of patients treated by the

organization. Also, there should be adequate equipment to treat the type of disabilities accepted by the organization.

NOTE: ***OCCUPATIONAL THERAPY SERVICES CANNOT BE SUBSTITUTED FOR PHYSICAL THERAPY SERVICES. In other words, the OPT cannot provide solely occupational therapy services. Occupational therapy services may be provided in addition to physical therapy or speech-language pathology services.***

I-55

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review personnel rosters for adequacy of qualified professionals. Review facility for types and number of equipment available for patients.

NOTE: *If the rehabilitation agency is not providing either physical therapy or speech pathology services, the most appropriate Tag to cite would be I7 since the organization would not be in compliance with all applicable Federal, State, local laws and regulations.*

B - Major Sources of Information

- Physician orders, plans of care, and physical therapy evaluations and progress notes;
- Patient care policies—such policies should include a description of their scope of services, admission and discharge criteria. The facility must appropriately refer individuals who have needs that exceed their scope of service;
- Personnel records--job descriptions, employee qualifications, and current licensure information; and
- Clinical records.

C - Standards

§485.713(a) Standard: Adequate Program

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

(1) The organization is considered to have an adequate outpatient physical therapy program if it can:

- (i) Provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity;*

- (ii) *Conduct patient evaluations; and*
 - (iii) *Administer test and measurements of strength, balance, endurance, range of motion, and activities of daily living.*
- (2) *A qualified physical therapist is present or readily available to offer supervision when a physical therapist assistant furnishes services:*
- (i) *If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, evaluation and re-evaluation.*
 - (ii) *When a physical therapist assistant furnishes services off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.*

An adequate outpatient physical therapy program includes:

- (a) *Provision of services using therapeutic exercises and the modalities of heat, cold, water and electricity to provide the range of therapy services necessary to treat individuals with the types of disabilities it accepts for service;*
- (b) *Conduct patient evaluations; and*
- (c) *Administer tests and measurements of strength, balance, endurance, range of motion and activities of daily living. It is possible that not all patients will receive every modality listed above. The plan of care should address the modalities that are medically necessary for the treatment of the patient's condition.*

I-56

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review patient care policies and procedures to assess the adequacy of the organizational program.

Physical therapy services are to be rendered only by qualified physical therapists or qualified physical therapist assistants under the supervision of qualified physical therapists. A qualified therapist must be onsite for evaluations and re-evaluations of patients. A physical therapist is readily available to offer supervision to a physical

therapy assistant according to the organization's policies and procedures but when a physical therapy assistant furnishes services offsite, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least every 30 days to observe the actual performance of the assistant. Only physical therapists may supervise physical therapy assistants. Only occupational therapists may supervise occupational therapy assistants.

Such supervision may include:

- Specific instructions regarding the treatment regimen;
- An explanation of responses to treatment indicative of adverse patient reactions;
- Discussions between the physical therapist and the physical therapist assistant; and
- *State practice acts and rules may include additional supervision requirements.*

NOTE: *This does not mean the physical therapist must be onsite full-time but must be able to respond and to be physically available onsite within a reasonable period of time to provide consultation in case of an unusual occurrence.* Response time is based on the condition of the patient, the patient's previous response to treatment, organization staffing, and competency of available personnel. For example, where the patient's previous response to treatment had been adverse, thereby possibly requiring that, in the future, the physical therapist keep himself readily available to provide needed supervisory assistance, the physical therapist should arrange times and schedules to allow for minimal delay in providing such assistance.

I-56

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review organizational policies regarding supervision and supervisory visits. Interview staff regarding supervision of assistants.

§485.713(b) Standard: Facilities, and Equipment

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.

All equipment should be maintained according to manufacturer's guidelines.

NOTE: Where patient privacy is required, this may be accomplished through utilization of individual treatment booths, folding screens, draw curtains, etc.

I-57

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review patient care policies and procedures and tour clinic to assess the adequacy of equipment and facility to treat the disabilities it has accepted for service. Review organizational procedures and speak with staff to ensure equipment is being maintained according to manufacturer guidelines.

§485.713(c) Standard: Personnel Qualified to Provide Physical Therapy Services

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Physical Therapy services are provided by, or under the supervision of a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.

The number of qualified physical therapists and qualified physical therapist assistants (if applicable) should be able to adequately and effectively provide services to patients. Adequate service cannot be determined *based upon* the mere proportion of the staff to patient ratio, *but rather*, it is to be based on knowledge of the types of patients treated and the type, amount, frequency, and duration of treatment required. *The qualified physical therapist is either on the premises or readily available during all hours of operation.*

I-58

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

To more accurately determine the sufficiency of personnel, review clinical records, together with the patient care policies, personnel records, and patient treatment schedules. Interview patients regarding availability of staff during scheduled treatment times.

§485.715(d) Standard: Supportive Personnel

If personnel are available to assist qualified physical therapists by performing services incident to physical therapy that do not require professional knowledge and skill, these

personnel are instructed in appropriate patient care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.

Physical therapy aides, or individuals with less than assistant level qualifications, must be directly supervised by a qualified physical therapist. The physical therapist must be in the immediate vicinity and available to provide assistance and direction throughout the time services are provided.

Even if an aide is assisting a qualified physical therapy assistant in some activity, ultimate responsibility for the aide's activities rests with the qualified physical therapist. *In the provision of physical therapy services, any staff other than the qualified physical therapist or physical therapy assistant is considered supportive personnel.*

I-63

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review organization policies and procedures to determine the job responsibilities of the supportive personnel.

§485.715 Condition of *Participation*: Speech Pathology Services

If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objective.

A - General

The speech pathology services provided should be such that patients accepted for treatment are able to receive services as medically indicated. The personnel and equipment necessary to effectively treat those patients may, in part, be dictated by the type of patients ordinarily accepted for treatment.

I-150

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review personnel rosters and patient census to determine that the organization provides sufficient personnel to adequately serve the patients it accepts for services.

B - Major Sources of Information

- Physician orders, plans of care, and speech pathology evaluations and progress notes;
- Patient care policies;
- Personnel records--job descriptions, employee qualifications, and current licensure information; and
- Clinical records.

§485.715(a) Standard: Adequate Program

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The organization is considered to have an adequate outpatient speech pathology program if it can provide the diagnostic and treatment services to effectively treat speech disorders.

I-151

Review the organization's patient care policies and clinical records to ascertain the adequacy of the speech pathology program.

§485.715(b) Standard: Facilities and Equipment

The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.

Space suitable for treatment must be available.

I-152

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Observe the clinic area to determine the adequacy of space and equipment.

§485.715(c) Standard: Personnel Qualified to Provide Speech Pathology Services.

Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume and diversity of

speech pathology services offered. At least one qualified speech pathologist is present at all times when speech pathology services are furnished.

The number of qualified speech pathologists should be adequate to effectively provide services to patients. As in the case of the physical therapist, this number is related to types of patients treated, the specifics of the plan of care, and the time required to carry out the plan.

Unlike physical therapy services where, at certain times, the application of certain modalities does not require the presence of the physical therapist, effective speech pathology treatment necessitates the continuing presence of the speech pathologist. Therefore, no formula utilizing numbers of physical therapists as a base for comparison can be used when determining whether or not the number of qualified speech pathology personnel is adequate.

I-153

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

At least one qualified speech pathologist must be present at all times when speech pathology services are provided as there are no recognized speech pathology assistants. Review personnel records to determine whether the speech pathologist is qualified to perform speech pathology services (most states require licensure or certification).

§485.717 Condition of Participation: Rehabilitation Program

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

This condition and its standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to whom the agency furnishes services. (The hospital, SNF, or NF is responsible for ensuring that qualified staff furnish services for which they arrange or contract for their patients.) The rehabilitation agency provides, in addition to physical therapy and/or speech-language pathology services, social or vocational adjustment services to all of its patients who need them. The agency provides for special qualified staff to evaluate the social and vocational factors, to counsel and advise on the social or vocational problems that arise from the patient's illness or injury, and to make appropriate referrals for needed services.

A - General

A rehabilitation agency must provide either physical therapy or speech pathology services plus a rehabilitation program which includes, at a minimum, social and/or

vocational adjustment services. Such services may be furnished directly or under arrangement.

*The rehabilitation agency is required to provide social or vocational adjustment services to all patients in need of such services. A qualified therapist can gather and document evidence regarding the need for social or vocational services via a screening tool or other written method deemed appropriate by the rehabilitation agency. This written documentation must be reviewed by the social worker, vocational adjustment specialist, or psychologist who will then determine the patient's needs for further evaluation. This process must be documented in the patient's clinical record. If further evaluation or services are needed, the agency's special qualified staff must provide them or make appropriate referrals. **Under no circumstances may a patient determine his or her vocational needs.***

However, there are circumstances when the provision of these services to certain patients by the rehabilitation agency would be unnecessary or would duplicate similar services provided by other organizations. The rehabilitation agency is neither required to evaluate patients, nor to provide social or vocational adjustment services to patients, under any of the following situations:

- The patient is receiving social or vocational adjustment services as an inpatient or outpatient of another provider or supplier of services, and a written agreement or contract between the rehabilitation agency and the provider or supplier specifies that the provider or supplier is responsible for social or vocational adjustment services for all patients receiving OPT/OSP from the rehabilitation agency.
- The other provider or supplier agrees in the written contract with the rehabilitation agency to clearly mark or identify the files of patients receiving OPT/OSP who have previously been evaluated for social or vocational adjustment services. A separate evaluation of those patients for social or vocational adjustment services by the rehabilitation agency is not required.
- The OPT/OSP provider provides diagnostic or therapeutic services to individuals for whom another agency or organization has overall responsibility.

Social or vocational adjustment services may be provided either on the premises or off the premises of the organization (e.g., in the office of the psychologist).

I-67

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the organization's policies and procedures and discuss with staff the methods to determine whether a patient requires social/vocational services. Review

staff meeting minutes or patient care meeting minutes. *Is the social worker or vocational specialist part of this meeting?*

B - Major Sources of Information:

- Contract for services under arrangement;
- Personnel records - job descriptions, employee qualifications and health examinations as specified;
- Clinical records;
- Patient care policies.

C - Standards:

§485.717(a) Standard: Qualifications of Staff

The agency's social or vocational adjustment services are furnished as appropriate, by qualified psychologist, qualified social workers, or qualified vocational specialists. Social or vocational adjustment services may be performed by a qualified psychologist or qualified social worker. Vocational adjustment services may be furnished by a qualified vocational specialist.

I-68

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review personnel folders to determine if the individuals providing social or vocational services meet the licensure, certification, registration, or other applicable qualifications of the state in which the services are being provided.

§485.717(b) Standard: Arrangements for Social or Vocational Adjustment Services

- (1) If a rehabilitation agency does not provide social or vocational adjustment services through salaried employees, it may provide those services through a written contract with others who meet the requirements and responsibilities set forth in this subpart for salaried personnel.*
- (2) The contract must specify the term of the contract and the manner of termination or renewal, and provide that the agency retains responsibility for the control and supervision of the services.*

If an agency does not provide social or vocational adjustment services through its own employees, such services may be provided by means of written agreements with individuals or organizations. Their contracts must specify the agency's responsibility, control and supervision over the services and must *detail the manner of termination or renewal of the contract*. The appropriate professional staff (psychologists, social

workers, vocational specialists) are responsible for developing, in conjunction with the physician, the regimen of social or vocational adjustment services to be provided to individuals requiring such services, and must assume the professional and administrative responsibility for services provided under arrangements.

I-72

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the contracts to assure that the agency's responsibility is detailed.

§485.719 Condition of *Participation*: Arrangements for Physical Therapy and Speech Pathology Services to be Performed by Other Than Salaried Rehabilitation Agency Personnel

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

§485.719(a) Conditions

If an organization provides outpatient physical therapy or speech pathology services under an arrangement with others, the services are to be furnished in accordance with the terms of a written contract, which provides that the organization retains professional and administrative responsibility for, and control and supervision of, the services.

A - General

The rehabilitation agency has professional and administrative responsibility for the physical therapy and speech pathology services provided under an arrangement.

I-79

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review contracts to assure that the agency retains professional and administrative responsibility for any services provided under arrangement.

B - Major Sources of Information

- Contract for services under arrangement;
- Personnel records - job descriptions, employee qualifications and health examinations as specified;

- Clinical records; and
- Patient care policies.

C - Standards

§485.719(b) Standard: Contract Provisions

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The contract:

- (1) Specifies the term of the contract and the manner of termination or renewal;*
- (2) Requires that personnel who furnish the services meet the requirements that are set forth in this subpart for salaried personnel; and*
- (3) Provides that the contracting outside resource may not bill the patient or Medicare for the services. This limitation is based on §1861 (w)(1) of the Act, which provides that:*
 - (i) Only the provider may bill the beneficiary for covered services furnished under arrangements; and*
 - (ii) Receipt of Medicare payment by the provider, on behalf of an entitled individual, discharges the liability of the individual or any other person to pay for those services.*

Organizations can provide outpatient therapy services under arrangement with others. These services are to be furnished in accordance with a written contract. The terms of the contract provide that the organization maintains professional and administrative responsibility for, and control and supervision of, the services. The terms also include termination/renewal procedures as well as qualifications to be met by those furnishing services under arrangements. Only the agency, not the contracted outside resource, may bill for services performed by the contracted resource.

I-80

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the contracts to assure that the organization has specified the qualifications the outside service provider must meet. The contract should state that the outside service provider may not bill for services rendered.

§485.721 Condition of **Participation**: Clinical Records

The organization maintains clinical records on all patients in accordance with accepted professional standards and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

A - General

The clinical record serves as a basis for documentation of medical care rendered to the patient. Clinical records should contain at least the following documentation: *Progress notes, monthly summaries, records of communication with the patient's physician and other therapists and discharge summaries.*

In addition to serving as a basis for documentation of care rendered to patients, clinical records provide evidence of the organization's implementation of policies and procedures as they relate to patient care.

I-96

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the clinical record to determine whether the content of the clinical record presents a total or, at a minimum, an adequate picture of the care being given and that documentation by those under contract meets the documentation standards of the organization.

Review a sample of all clinical records, including those patients whose treatment is provided under arrangement, to make certain that evaluations, progress notes, and other pertinent clinical material are present and that the clinical records containing applicable information for all patients are maintained on the premises of any location at which services are rendered. However, if the surveyor is surveying only the primary location, clinical records should be available to the surveyor for review, during the course of the survey, regardless of where the records are kept.

B - Major Sources of Information

- Active and closed clinical records; and
- Policies regarding retention and confidentiality of clinical records.

C - Standards

§485.721(a) Standard: Protection of Clinical Record Information

Clinical records are to be stored where they are protected from fire and unauthorized use. ***The organization must make every effort to safeguard the medical records against unauthorized access/use particularly if the organization shares space with another entity.*** Organization policies are to note to whom records or copies thereof may be provided, the use to which the material may be put, and the circumstances describing the return of such material. For the release of all material not authorized by law, the patient's written consent is required.

I-154

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the organization's policies for securing and safeguarding clinical records against loss, destruction, or unauthorized use.

§485.721(b) Standard: Content

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

- (1) Documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services furnished;*
- (2) Identification data and consent forms;*
- (3) Medical history;*
- (4) Report of physical examinations, if any;*
- (5) Observations and progress notes;*
- (6) Reports of treatments and clinical findings; and*
- (7) Discharge summary including final diagnosis(es) and prognosis.*

Virtually all clinical records should contain an assessment of the needs of the patient (initial evaluation and reevaluations where appropriate), plan of care (including the types, amount, duration and frequency of services provided), identification data (name and address of patient), observations and progress notes, reports of treatments and clinical

findings, and discharge summary. Other documentation should include coordination efforts between professionals providing services.

However, consent forms, medical history and report of the physician's physical examination may or may not appear in clinical records. This information would need to appear only where *demonstrably* relevant to patient treatment. Where medical history does appear in clinical records, it may not have been that transmitted by the physician but, rather, may have been obtained from the patient when the past and present history was related. *Progress notes should be updated in the patient's clinical record at least weekly.*

Where emergency care is provided, the clinical record should include the following: Type of care rendered, date, personnel involved, and the incident that precipitated the need for such care.

I-97

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Examine a substantial number of both active and closed clinical records, selected on a random basis and not restricted to those of Medicare patients.

§485.721(c) Standard: Completion of Records and Centralization of Reports

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician signs the entries that he or she makes in the clinical record.

If omission of any pertinent information is noted in the clinical records, additional clinical record reviews should be undertaken to determine the prevalence of such omissions.

A discharge summary should include the date and reason for discharge; a brief summary of the current status of the patient at the time of discharge; and, where applicable, provision for referral of the patient to another source for continuing care.

Regardless of whether the organization provides services through its own employees or through an arrangement with others, all materials that are pertinent to the patient's treatment are to be part of the clinical record, which is to be maintained on the premises of any location at which services are rendered. All information appearing in the clinical record is to be dated appropriately, signed, and incorporated weekly into the clinical record.

(I-155)

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The survey should indicate on the Survey Report Form the number of clinical records reviewed and the number and types of deficiencies found in each. Where record reviews prompt questions concerning patient care, the surveyor should request additional information and assistance from the appropriate organization personnel.

§485.721(d) Standard: Retention and Preservation

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Clinical records are retained for at least:

- (1) The period determined by the respective State statute, or the statute of limitations in the State, or*
- (2) In the absence of a State statute:
 - (i) Five years after the date of discharge, or*
 - (ii) In the case of a minor, 3 years after the patient becomes of age under State law or 5 years after the date of discharge, whichever is longer.**

I-108

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the organization policy pertaining to retention and preservation of clinical records and verify that such policy is consistent with applicable State law or regulation where such exists. Verify that there is a provision in organization policies for the retention and transfer of clinical records if the organization ceases to function.

§485.721(e) Standard: Indexes

Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical information and retrieval of records for research or administrative action.

Clinical records are indexed according to the last name of each patient, but in some cases indexing may be according to file identification numbers assigned to patients on admission to the organization. This system may be utilized for indexing either active and/or discharged patient clinical records as determined by organizational need.

I-156

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the organizational policies/procedures regarding the system for indexing clinical records.

§485.721(f) Standard: Location and Facilities

The clinical records are to be easily retrievable and available to all professional staff members of the organization and other authorized individuals. Clinical records may be maintained at a site other than the primary location (the site issued the provider agreement/number) if the beneficiary receives outpatient therapy services at that other site. All records must be **available** to the surveyor **during the course of the survey regardless of where the records are kept.**

I-157

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

NOTE: Records may be delivered to the surveyor electronically or by other means as long as the delivery is within a reasonable amount of time during the course of the onsite survey.

§485.723 Condition for Participation: Physical Environment

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

A - General

The structure housing the organization is such that it is held "open to the public." Patient treatment areas and other locations associated with organization function (e.g., storage and restrooms) are to be physically separated from non-organization areas. Restrooms, however, need not be located directly in the treatment area, but may be located, for example, down a hallway so long as they are easily accessible by non-ambulatory and semi-ambulatory individuals.

The physical environment should be considerate of patient privacy (away from public viewing). Patient privacy may be assured through utilization of individual treatment booths, folding screens, draw curtains, etc.

I-117

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

In order to ensure the safety of patients, personnel, and the public, examine the physical plant of the organization and ascertain whether or not it is maintained consistent with State and local building, fire, and safety codes.

B - Major Sources of Information

- Applicable Federal, State and local laws;
- Inspection reports of State and local building and fire authorities; and
- Organization policies regarding maintenance of equipment, building and grounds.

C- Standards

§485.723(a) Standard: Safety of Patients

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The organization satisfies the following requirements:

- (1) It complies with all applicable State and local building, fire, and safety codes;*
- (2) Permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the premises considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of the premises. Fire regulations are prominently posted;*
- (3) Doorways, passageways and stairwells negotiated by patients are:*
 - (i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs),*
 - (ii) Free from obstruction at all times, and*
 - (iii) In the case of stairwells, equipped with firmly attached handrails on at least one side.*

- (4) *Lights are placed at exits and in corridors used by patients and are supported by an emergency power source;*
- (5) *A fire alarm system with local alarm capability and, where applicable, an emergency power source is functional;*
- (6) *At least two persons are on duty on the premises of the organization whenever a patient is being treated;*
- (7) *No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.*

Areas *of the organization* considered to be especially hazardous (e.g., rooms or spaces used for combustible supplies and equipment) are to be equipped with a State fire authority approved, **permanently attached**, automatic fire extinguishing system, or shall be separated from the balance of the building by 1-hour *rated* fire resistant barriers. All areas occupied or accessible to the organization for use during emergency or non-emergency activity, including corridors and stairwells, are to be protected by easily accessible fire extinguishers (e.g., the case of an organization located in a multilevel structure, *irrespective of* whether the entire structure, or only a portion thereof, is utilized). The doorways and passageways shall be *free of obstruction* to allow for ease in patient movement into and within the organization and shall be wide enough to *accommodate the type and condition of patients (i.e., in wheelchairs, etc.) accepted for treatment*. Stairwells should include handrails on at least one side and should be free from obstruction at all times.

An emergency power source (e.g., battery or auxiliary generator) is available to assure adequate lighting during emergency operation within the treatment areas and those passageways, stairwells, and exits (as noted above) accessible to the organization. In cases of power outage, the emergency power source should respond either automatically or require only minimal activation effort.

The fire alarm system should be adequate to alert organizational personnel in time to *permit* safe evacuation of the building. The premises of the organization are to be safeguarded by a fire alarm system or automatic detection system that is in operational condition. Provision is also to be made for an internally audible manual alarm capability, either separately contained, or functioning in combination, with the fire alarm or automatic detection system. In the absence of State or local requirements, the above systems are to be approved by the State Fire Marshal's Office. A system without the capacity for manual activation in response to a fire would not serve to alert other personnel, patients, and the public of danger and the need for action. Where the alarm system is activated by a disruption in the organization's electrical system, or is in other ways dependent on it, an emergency power source (e.g., battery or auxiliary generator) should be available to serve as backup.

The building housing the organization should be free of hazardous occupancies or activities such as the manufacturing of combustible materials.

I-118

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Verify that applicable State and local building, fire, and safety codes are met and review available reports of State and local personnel responsible for enforcement of the above.

§485.723(b) Standard: Maintenance of Equipment, Building, and Grounds

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The organization establishes a written preventive-maintenance program to ensure that:

- (1) The equipment is operative and is properly calibrated, and*
- (2) The interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel, and the public.*

All equipment should be inspected by the organization at least yearly or in accordance with manufacturers' guidelines and a *maintenance scheduled maintained*. Such inspection is determined in part by present equipment condition and its frequency of use, and is to be outlined in written procedures that include the following:

- Equipment to be inspected;
- A brief statement concerning the general inspection process; and
- Frequency of inspection for each piece of equipment.

For all electrically powered patient care equipment, appropriate manufacturer's operating and maintenance information should be on file. The surveyor should review this information and ascertain what specific recommendations, if any, are made for equipment calibration checks, periodic maintenance procedures, etc. Then, through copies of service repair statements or other documentation, determine whether such recommendations were followed.

I-158

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review organization maintenance checklists. Note any hazards to the health and safety of patients, personnel, and the public (e.g., broken window and door panes,

obstruction of passageways, and dangerous floor surfaces) on the Survey Report Form (CMS-1893).

§485.723(c) Standard: Other Environmental Considerations

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public.

- (1) Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through windows, mechanical means, or a combination of both;*
- (2) Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow use by non-ambulatory and semi-ambulatory individuals; and*
- (3) Whatever the size of the building, there is an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.*

In order to make the organization's environment comfortable, sanitary and functional for patients, personnel and the public, the following provisions should be considered: lighting, sounds, temperature, ventilation, toilet facilities and space for the organization to comfortably function. Where necessary, ramps should be available to provide for easy access to facilities and equipment. Examination and treatment areas should be large enough to enable effective application of the plan of care. Where underwater exercise is utilized, a safe and effective patient lift device is available.

I-130

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Verify that temperature control mechanisms maintain the temperature at a comfortable and constant level. Verify that restroom/toilet facilities are handicapped accessible. Observe all areas within the organization. Is the space adequate for storage, treatment, etc?

§485.725 Condition of Participation: Infection Control

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The organization that provides outpatient physical therapy services establishes an infection control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

A - General

An infection control committee, applicable for organizations offering physical therapy services, has overall responsibility for ensuring that environmental infection hazards are controlled. *The committee should consist of staff representing the various professional services provided by the organization and should ensure that the organization has up-to-date infection control policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are being executed.*

I-159

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the organization's Infection Control policies and procedures. Does the organization have the necessary housekeeping staff and supplies to maintain a sanitary environment.

B - Major Sources of Information

- Written policies and procedures; and
- Minutes of the infection control committee.

C - Standards

§485.725(a) Standard: Infection Control Committee

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The infection control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed

Meetings are to be held at least annually with minutes being kept, and at least two or more individuals should constitute the committee. The committee should be composed of persons whose educational background and experience (e.g., M.D., R.N., and other interested professionals) is adequate to perform this function. The administrator, in the

case of a clinic or rehabilitation agency, should assume responsibility for selecting the professionals to serve on the committee.

Written procedures covering infection control and cleanliness of certain physical therapy equipment such as whirlpools, paraffin baths, and moist hot pack units, *as well as provisions for disposal of bio-hazardous materials* should be available for review. This is particularly important in cases where whirlpools are used for debridement of wounds. *Written procedures covering infection control should also be available for any of the other professional services (i.e. equipment used by occupational therapy or speech-language pathology).*

I-160

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The surveyor should review the policies and procedures *and minutes of the annual meeting* for preventing, controlling, and investigating infections and should ascertain whether the recommendations of the committee are acted upon.

§485.725(b) Standard: Aseptic and isolation techniques

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.

Personnel are to follow written procedures for effective aseptic techniques.

I-161

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the aseptic procedures developed and ascertain, through a discussion with available professional personnel and review of major sources of information, that the procedures are communicated to the staff. *Observe staff during the survey and note if staff are not following the correct procedures outlined in policies. Review the organization's documentation of its aseptic procedures—is it reviewed annually and updated as needed (look for dates).*

§485.725(c) Standard: Housekeeping

(1) The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A fulltime

employee is designated as the one responsible for the housekeeping services and for supervision and training of housekeeping personnel;

(2) An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization or outside resource or both meet the requirements of the standard.

The organization identifies the individual(s) assigned primary responsibility for housekeeping duties. When there is a contract with an outside resource to provide such services, the organization retains responsibility for the housekeeping duties. *The organization is responsible for employing sufficient housekeeping staff to maintain a clean, safe environment.*

I-162

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Inspect the organization for cleanliness and orderliness especially with regards to equipment, floors, tables, etc. Review contracts (if the organization contracts with outside housekeeping services) to ensure that the organization has retained responsibility and oversight for the housekeeping services performed by the outside source.

§485.725(d) Standard: Linen

The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

Organization has a new supply of fresh clean linen, essential for proper care and comfort of all patients treated, plus an additional supply to provide for any possible increased usage that is to be stored in clean areas and available for daily use.

I-163

Verify that soiled linen is removed from patient areas at least daily and stored in an area away from patients, personnel, and the public and is stored away *from clean linen.* Review policies and procedures for handling linen and see that policies and procedures are being followed.

§485.725(e) Standard: Pest Control

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The organization premises are maintained free from insects and rodents through operation of a pest control program.

The organization's premises should be free from insects and rodents.

I-164

Review the organization's written policy covering the pest control program.

§485.727 Condition of Participation: Disaster Preparedness

The organization has a written plan, periodically rehearsed with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster.

A - General

A well developed disaster plan must be documented and posted in areas accessible for continuing personnel review.

I-165

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

During the survey, ask staff members to describe their individual roles in the disaster plan.

B - Major Sources of Information

- Disaster plan; and
- Documentation as to ongoing training sessions and dates of disaster drills.

C - Standards

§485.727(a) Standard: Disaster Plan

The organization has a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes:

- (1) Transfer of casualties and records;*
- (2) Location and use of alarm systems and signals;*

- (3) *Methods of containing the fire;*
- (4) *Notification of appropriate persons; and*

- (5) *Evacuation routes and procedures.*

Ensure that the written plan is operational and contains procedures to be followed, evacuation routes and assignment of staff responsibilities in the event of a disaster.

I-166

Verify that the description of the location of the alarms systems is accurate. *Verify that staff members know the sequence of events for which they are responsible during a fire or other disaster. Do staff members know the evacuation routes for patients in wheelchairs or with crutches?*

§485.727(b) Standard: Staff Training and Drills

All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his assigned role in case of a disaster.

The organization should have annual staff training and disaster drills for all salaried and contracted employees. All personnel are to be exposed to practice drill situations calling for the exercise of their responsibilities as stated in the disaster plan.

I-167

Verify that disaster drills are carried out at least annually and include all salaried and contracted employees, and that the date and the names of those persons taking part are documented. Annual drill disasters must be carried out annually at extension locations.

§485.729 Condition of *Participation*: Program Evaluation

The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.

A - General

At least once a year the organization should assess the performance of its total operation. Total operation refers not only to those services provided to patients, but also to the broader concepts of overall organization administration, including, but not limited to, policies and procedures, personnel, fiscal, patient care, etc. Procedures *must be in place*

which provide for an evaluation of the total organization program. *Written reports of the results of the evaluation should be maintained and the facility should have a performance improvement plan that collects data about the organization's performance on an ongoing basis.* The evaluation should be conducted by the professional staff of the organization and outside professionals, where appropriate. These reports should contain the names of those participating in the evaluation, the results, and expected action, if indicated.

I-168

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review dated reports of the most recent program evaluations.

B - Major Sources of Information

- Written policies and procedures concerning the evaluation process;
- Patient care policies; and
- Minutes of meetings on program evaluation.

C - Standards

§485.729(a) Standard: Clinical Record Review

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to ensure that established policies are followed in providing services.

A substantial sample of records reviewed should be randomly selected from the active and closed files. Each service offered by the organization should be represented in the sample. In instances where a patient is receiving both physical therapy and speech pathology services, the record may be included in the sample of each service rendered. The clinical record review committee is composed of health professionals representing those services provided *directly and, if applicable*, under arrangement, by the organization. It is not necessary that those committee members be employees of the organization. Administrative personnel would ordinarily be committee participants.

I-169

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review minutes of the organization's clinical record review committee. *Do the minutes indicate corrective action to be taken if the organization finds that established policies are not being followed?*

§485.729(b) Standard: Annual Statistical Evaluation

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es) sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

The organization must conduct an annual evaluation of statistical data. Each organization may decide the types of data it wishes to collect (in addition to numbers of patient visits, types of patients, etc.). Some organizations may find that a quarterly report, as opposed to an annual report, would prove more beneficial in determining the effect of organizational policies. Correct and consistent application of policies will, to some extent, be reflected in the statistical evaluation, and, where policy has not been followed, the evaluation can serve as a guidepost for any necessary change.

I-170

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The surveyor should review and compare the prior years and current statistical reports to determine that the data similar in character to the organization's program evaluation purposes, is being kept.

GENERAL NOTE:

If during the survey process, the extension location(s) is found to be out of compliance with a CoP, the provider as a whole is considered out of compliance.

State Operations Manual

Appendix K - Guidance to Surveyors: Comprehensive Outpatient Rehabilitation Facilities

(Rev. 13, 10-21-05)

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General Comments

Explanation of Conditions of Participation for Comprehensive Outpatient Rehabilitation Facilities

4 2CFR 485.51 Definition of a CORF

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

*A CORF is established and operated **exclusively** for the purpose of **providing diagnostic, therapeutic, and restorative services** to outpatients for the **rehabilitation of injured, disabled, or sick persons**, at a single fixed location, by or under the supervision of a physician **and meets all the requirements of Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities.***

42 CFR 485.54 *Condition of Participation:* Compliance With State and Local Laws

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility and all personnel who provide services must be in compliance with applicable State and local laws and regulations.

A - General

In order to assure that the Comprehensive Outpatient Rehabilitation Facilities (CORF) and staff furnishing services are in possession of current licenses as required by State and local laws, licenses should be available for review.

If the facility has not met local and State building, fire and safety codes or doesn't have the appropriate licenses, the facility should be refused admission into the program or termination proceedings should be initiated, whichever is appropriate.

I-501

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the licenses to assure the licenses are current and are applicable to the State in which the provider is providing services.

B - Major Sources of Information

- 1.*** State and local laws governing health care; building, fire and safety codes;
- 2.*** Applicable State and local licenses and organization personnel records containing up-to-date information; and

3. Written policies pertaining to communicable and reportable diseases, conforming to applicable State and local laws.

C - Standards

§485.54(a) Standard: Licensure of Facility

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

If State or local law provides for licensing, the facility must be currently licensed or approved as meeting the standards established for licensure.

The facility must meet all building, fire and safety codes where these are required for licensure before a facility would be eligible for certification. Ascertain that all State and local licenses, permits and approvals that govern the facility's operation are current and valid.

I-502

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

If the proper authorization(s) has not been granted, or has been temporarily revoked or suspended, the facility should be found in noncompliance with this standard.

If a facility has been issued a provisional license, permit or approval, determine whether the limitation(s) prevents the facility from complying with the conditions of participation.

I-502

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Document the reason for this issuance including the limitation(s) imposed on the facility's operation.

Facilities exempt from State licensure, must be approved by the State as meeting the standards established for licensure. Examples of exempted facilities may include facilities that operate on a Federal reservation under agreement with the Department of Health and Human Services and facilities operated by a State, city or county health department.

§485.54(b) Standard: Licensure of Personnel

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Personnel that provide service must be licensed, certified, or registered in accordance

with applicable State and local laws.

Personnel providing services at the CORF must be licensed, registered or *certified* when licensure, registration or *certification* is applicable. This includes employees, independent contractors and individuals from organizations with which the CORF has an arrangement to provide services.

I-503

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review policies and procedures regarding the CORF's verification of qualified personnel.

Verify licensure or registration of personnel by reviewing a central State listing or other evidence such as wallet size identification cards.

42 CFR 485.56 *Condition of Participation:* Governing Body and Administration

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must have a governing body that assumes full legal responsibility for establishing and implementing policies regarding the management and operation of the facility.

A - General

The CORF must have a governing body which is responsible for its policies and operation, and which appoints an individual to act as the facility administrator. A group of professional personnel must develop and review policies that govern the CORF services.

The governing body is the Board of Directors or Trustees of a corporation or the owner(s), in the case of a proprietary agency, or others who assume legal responsibility for the facility. While there are no requirements that the governing body follow a prescribed meeting schedule, there should be evidence that the governing body takes an active role in the overall operation of the CORF. This includes the development and review of the institutional budget plan, and knowledge of and concurrence with all patient care and major operational policies, *utilization review and quality improvement activities.*

B - Major Sources of Information

- Articles of incorporation, bylaws, policy statements, etc.
- Minutes of governing body, staff and patient care policy meetings.
- Organization chart showing administrative framework

- Personnel records -- job descriptions and personnel qualifications
- Institutional budget plan
- Management contracts
- Patient care policies
- Clinical records
- *Utilization Review/Quality Improvement Reports*

I-505

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Assess the effectiveness and adequacy of the governing body's management and operation of the facility by reviewing documentation of the governing body's activities. This documentation should include minutes of the governing body, policy statements, bylaws and delegations of authority.

C - Standards

§485.56(a) Standard: Disclosure of Ownership

The facility must comply with the provisions at 42 CFR Part 420, Subpart C that require health care providers and fiscal agents to disclose certain information about ownership and control.

The facility must disclose certain information about its ownership and control in complying with 42 CFR Part 420, Subpart C. Fiscal Intermediaries will review and verify the information provided on the Form CMS—855A (Application for Health Care Providers that will Bill Medicare Fiscal Intermediaries), prior to the state's survey of a new CORF or when a CORF makes a change (e.g., change of ownership (CHOW) or change of address).

I-506

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review ownership documents for signature and completeness.

§485.56(b) Standard: Administrator

The governing body must appoint an administrator who:

(1) Is responsible for the overall management of the facility under the authority

delegated by the governing body;

(2) Implements and enforces the facility's policies and procedures;

(3) Designates, in writing, an individual who, in the absence of the administrator, acts on behalf of the administrator; and

(4) Retains professional and administrative responsibility for all personnel providing facility services.

The qualifications of an administrator may vary among facilities, i.e., some administrators may be health professionals while others may be business managers. The administrator's basic responsibility regardless of the field of expertise is to assure that services are rendered in accordance with CORF policies and that there is efficient utilization of resources and coordination of services. The administrator should have a thorough working knowledge of the overall operation of the facility, including the scope of services provided, policies governing these services, budgetary and fiscal matters and the utilization and qualification of personnel.

I-507, I-508, I-509, I-511

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Discussion with the administrator will assist in determining depth of facility knowledge.

An administrator, especially of a large facility, generally functions on a full-time basis. However, a small facility may have a part-time administrator, e.g., one who also provides services as one of the professional personnel.

Determine if services are being provided in accordance with facility policies, that policies are current and reflect an acceptable standard of care, that care is coordinated among the professional staff and that there is efficient use of resources. If system problems are identified in any of these areas, consider a citation under governing body.

Facility policies must designate in writing an individual who acts on behalf of the administrator during a period of absence

I-510

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review facility policies to ensure the facility has named an individual who will serve as administrator in the administrator's absence.

§485.56(c) Standard: Group of Professional Personnel

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must have a group of professional personnel associated with the facility that:

- (1) Develops and periodically reviews policies to govern the services provided by the facility; and*
- (2) Consists of at least one physician and one professional representing each of the services provided by the facility.*

The group of professional personnel serves a very specific facility function, that is, to make certain that policies relating to patient care are realistic and best meet the needs of the facility and patients alike. Effective facility operation is dependent, in part, on workable policies especially those relating to: limitation of service capability, criteria for patient admission, etc. These policies must be developed and periodically reviewed by the group of professional personnel. The facility should be able to show that the group of professional personnel is carrying out its policy formulation and review function. The group must consist of at least one physician and one professional representing each of the services provided by the facility. The names of all group members must be available and evidence must confirm their participation in policy development and review.

All or part of the group of professional personnel, or a group of similar composition, can serve as the facility's utilization review committee. Although a similarly comprised group not associated with the facility can perform the utilization review function, it cannot develop and periodically review the facility's policies

I-512, I-513, I-514

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review facility policies and/or procedures or other documentation that reflects this function is being carried out (i.e., minutes of meetings, etc).

§485.56(d) Standard: Institutional Budget Plan

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must have an institutional budget plan that meets the following conditions:

- (1) It is prepared, under the direction of the governing body, by a committee consisting of representatives of the governing body and the administrative staff;*
- (2) It provides for:*

- (i) *An annual operating budget prepared according to generally accepted accounting principles;*
- (ii) *A three year capital expenditure plan if expenditures in excess of \$100,000 are anticipated, for that period, for the acquisition of land; the improvement of land, buildings and equipment; and the replacement, modernization, and expansion of buildings and equipment; and*
- (iii) *Annual review and updating by the governing body.*

In reviewing the facility's institutional budget plan, there must be evidence the plan has been prepared under the direction of the governing body (a committee composed of at least one member of the governing body and at least one member of the administrative staff). The CORF may have a 3-year capital expenditure plan if expenditures, in excess of \$100,000 are anticipated for that period of time (i.e., acquisition or improvement of land, replacement or modernization of equipment, buildings, etc.).

I-515, I-516, I-517

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the Institutional Budget Plan for evidence that the governing body annually reviews and updates the institutional budget plan. If the administrator states that there is no capital expenditure plan because no capital expenditure in excess of \$100,000 is anticipated, note on the Survey Report Form CMS -360.

§485.56(e) Standard: Patient Care Policies

The facility must have written care policies that govern the services it furnishes. The patient care policies must include the following:

- (1) A description of the services the facility furnishes through employees and those furnished under arrangements;*
- (2) Rules for and personnel responsibilities in handling medical emergencies;*
- (3) Rules for the storage, handling, and administration of drugs and biologicals;*
- (4) Criteria for patient admission, continuing care, and discharge;*
- (5) Procedures for preparing and maintaining clinical records on all patients;*
- (6) A procedure for explaining to the patient's family the extent and purpose of the services to be provided;*

- (7) A procedure to assist the referring physician in locating another level of care for patients whose treatment has terminated and who are discharged;*
- (8) A requirement that patients accepted by the facility must be under the care of a physician;*
- (9) A requirement that there be a plan of care established by a physician for each patient; and*
- (10) A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.*

These policies comprise the basic operating framework of the CORF and are critical to its effective operation. All policies must be in writing and documentation must verify the input of the group of professional personnel in policy development and review. The policies should be current, compatible with the CORF's provision of services and be responsive to the needs of the patients.

I-518

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Copies of all patient care policies should be reviewed.

In brief, patient care policies must reflect the following:

I-519

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

All services rendered by the CORF including those which are rendered by employees or by others furnished under an arrangement;

I-520

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A description of personnel tasks during medical emergencies and specific responsibilities, where assigned;

I-521

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The types of drugs and biologicals usually kept on the premises, their use, their manner of storage, who has access to these materials and a procedure for periodic review to determine the expiration date *of the drugs and biologicals*.

I-522

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

All criteria governing patient admission, continuing care and discharge. These criteria should coincide with professional staffing and must be as specific as possible. Factors governing admission may include geographic areas, ambulatory status of patients, specific diagnoses, patient ability to carry through on a home program, etc. Criteria developed for discharge may follow along the lines of specific levels of progress (attainment of goals), need for higher level of care etc;

The manner in which clinical record documentation is to be prepared and maintained. At a minimum, policies should state that all personnel performing services (i.e., those defined in the conditions of participation) must *authenticate* any entry they place in the patient's clinical record regardless of whether such personnel are employees of the facility or others. Clinical records must be maintained so that easy access is afforded all CORF personnel.

I-523

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The policy must require that documentation in the clinical records be sufficient to support reasons for admission, care and treatment and discharge/transfer status;

I-524

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A procedure for explaining a patient's treatment program to the patient and to the patient's family. In most cases this procedure would include a discussion of the diagnosis (es), the type and reasons for treatment, the treatment goal and the type of home program, where applicable, which will be developed. In general, unless the referring physician specifically notes that certain information is not to be revealed to the patient or family, the treatment program is to be discussed in detail and procedures are to be in effect for continuing discussions as they are warranted;

I-526, I-527

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A policy that requires all patients to be under the care of a physician and that a plan of treatment for each patient must be in effect;

I-525

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A procedure to assist the referring physician in locating another level of care for patients whose treatment has terminated and who are discharged; and

I-528

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

Review clinical records and utilization review committee minutes, to determine if policies have been developed for all aspects of care. Interview members of the professional staff to determine if they have a working knowledge of the policies.

§485.56 (f) Standard: Delegation of Authority

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The responsibility for overall administration, management and operation must be retained by the facility itself and not delegated to others:

(1) The facility may enter into a contract for purposes of assistance in financial management and may delegate to others the following and similar services:

(i) bookkeeping,

(ii) assistance in the development of an operating budget, and

(iii) purchase of supplies in bulk form, (iv) the preparation of financial instruments.

(2) When the services listed in paragraph (f)(1) of this section are delegated, a contract must be in effect and:

(i) May not be a term of more than 5 years,

(ii) Must be subject to termination within 60 days of written notice by either party,

- (iii) *Must contain a clause requiring renegotiation of any provision that CMS finds to be in contravention to any new, revised, or amended Federal regulation or law,*
- (iv) *Must state that only the facility may bill the Medicare program, and*
- (v) *May not include clauses that state or imply that the contractor has power and authority to act on behalf of the facility, or clauses that give the contractor rights, duties, discretions, or responsibilities that enable it to dictate the administration, management, or operations of the facility.*

A CORF may obtain assistance in financial management and delegate certain services, including bookkeeping, billing procedure and accounting system development, budget development, supply purchasing, and financial statement preparation. Where a CORF does obtain services from another entity, the CORF must have a contract for a term of not more than 5 years in effect. Such a contract must provide a 60 day right of termination, permit renegotiation of any term which CMS determines as contravening a Federal law or regulation, and not permit the contractor to act on behalf of the facility or to bill the Medicare program.

I-529, I-530, I-531

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review CORF contracts for adherence to this Standard.

42 CFR 485.58 *Condition of Participation:* Comprehensive Rehabilitation Program

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must provide a coordinated rehabilitation program that includes, at a minimum, physicians' services, physical therapy services and social or psychological services. The services must be furnished by personnel that meet the qualifications set forth in §485.70 and must be consistent with the plan of treatment and the results of comprehensive patient assessments.

A – General

CORFs must provide a coordinated, comprehensive, skilled rehabilitation program. In this instance, comprehensive means a broad array of services that must include, at a minimum, the following three “core” services: Physician services (rendered by a physician and defined in Standard (a): Physician Services of this appendix),

physical therapy services and social work or psychological services.

Coordinated means the rehabilitation plan of treatment is developed, periodically reviewed and modified as appropriate by the interdisciplinary treatment team members providing the rehabilitative care to the patient. Progress notes should reflect on-going communication and collaboration **among** the individual's treatment team members, the individual being served and members of the individual's family/support system, as appropriate. ***Review progress notes and other medical record entries for examples of on-going communication.***

Skilled rehabilitation **program** is defined as services requiring the skills of qualified professional personnel who have the expertise necessary to identify and treat the individual's functional, psychological, social and medical needs, such as a physical therapist, occupational therapist, social worker or psychologist. The skilled rehabilitation services provided must be designed to minimize impairment, reduce activity limitation or lessen participation restrictions.

Review medical record for examples of patient progress toward attaining rehabilitation goals set in plan of treatment. Maintenance therapy programs are not considered reasonable and necessary by Medicare. A therapist can develop a maintenance program for the patient to follow at home—this does not require the ongoing skills of a therapist.

Review a listing of the facility's CORF services to determine whether the required three ("core") services: physician services, physical therapy and social or psychological services are furnished. Review medical records for indication that patients are receiving the "core" CORF services and optional CORF services as indicated in the plan of treatment.

In addition, the CORF may provide any or all of the following optional CORF services: Occupational therapy, speech-language pathology, respiratory therapy, prosthetic and orthotic devices, nursing, drugs and biologicals, *DME and a single home visit, and be reimbursed for those services, only if they are part of a comprehensive, coordinated, skilled rehabilitation program.*** Nursing services, specified in the plan of treatment and any other nursing services necessary for the attainment of the rehabilitation goals, are provided by or under the supervision of a professional registered nurse. The services must be furnished by nursing personnel who meet the qualifications set in §485.70. The services must be consistent with the plan of treatment.**

I-532

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Verify the CORF is providing the three "core" CORF services.

I-532

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Ascertain, by record review and staff interview, whether the CORF is providing an individualized comprehensive, coordinated, skilled rehabilitation services program. The program should be directed at optimizing function and promoting interventions to increase the function of the persons served. .

NOTE: *Physician diagnostic and therapeutic services (e.g., evaluation and management services that are furnished to an individual patient) are not physician services covered under the CORF outpatient therapy benefit. When a physician personally performs these services, they are billable to the Part B carrier. Hyperbaric oxygen (HBO) services are considered physician therapeutic services and are not CORF services.*

As always, the services provided must be considered reasonable and medically necessary.

B - Major Sources of Information

Assimilation of information from patient care policies, plans of treatment, clinical records and staff interviews is necessary to obtain a clear picture of the CORF's operations (i.e., is the CORF following the intent of the regulations and providing a comprehensive rehabilitation program or is it primarily specializing in a particular type of the treatment (i.e., HBO, psychiatric nursing, infusion therapy)?

- 1. Policies and Procedures: Determine whether the CORF offers a comprehensive, integrated rehabilitation treatment approach. **Review policies and procedures, organizational charts and medical records for evidence of interdisciplinary treatment team meetings.***
- 2. Review organization chart showing administrative facility framework.*

C - Standards

§485.58(a) Standard: Physician Services

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

(1) A facility physician must be present in the facility for a sufficient time to:

- (i) Provide, in accordance with accepted principles of medical practice, medical direction, medical care services and consultation;*
- (ii) Establish the plan of treatment in cases where a plan has not been established by the referring physician;*
- (ii) Assist in establishing and implementing the facility's patient care policies;
and*
- (iv) Participate in plan of treatment reviews, patient case review conferences,*

comprehensive patient assessment and reassessments and utilization reviews.

(2) The facility must provide for emergency physician services during the facility operation hours.

Written documentation must indicate that a physician(s), (who meets the qualifications in the conditions of participation regulation at §485.70(a)), performs the required **CORF** physician services. Participation for at least one year in a residency program that provides training in the medical management of patients needing services such as orthopedics, neurology, neurosurgery, rheumatology, *physical medicine*, etc., meets the definition of facility physician. *Specialization in pulmonary medicine does not by itself satisfy the requirements for rehabilitation training. A facility physician who does not have specialized training in one of the approved rehabilitation disciplines may satisfy the qualification requirements through at least one year of work experience providing medical management services in a rehabilitation setting. Such services must include developing plans of treatment, participation in patient case review conferences, and establishing patient care policies for rehabilitation patients.* While it is preferable for this experience to have been full-time, part-time experience is acceptable. However, part-time experience should have been on a continuing weekly basis. The degree of time spent must confirm that required functions were accomplished.

I-533

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review physician hours.

Documentation must verify this training or experience. It might consist of a résumé, certificates of training or letters acknowledging completion of training or experience.

I-532, I-549

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review available material to verify compliance with physician qualification requirements at §485.70.

The facility physician may be associated with the facility on either a part-time or full-time basis. If part-time, it is important to determine that the physician is effectively performing required responsibilities. Review the activities of the group of professional personnel, utilization review process, patient records and reports of case review conferences to ascertain the extent of physician participation in patient care activities. The extent of physician participation can be determined, in part, by the type and volume of patients, scope of services and need for consultation and medical care services. Normally, greater physician participation will be required in a facility where the patients have multiple chronic disabilities, require several services, and require frequent changes in the plan of care than in

a facility where the patients have acute disabilities.

Generally, a facility physician may refer patients to the facility. CORFs may have a physician(s) providing physician services at the facility on a part-time basis and this physician(s) may have an office practice distinct from the CORF. In such cases this physician(s) may establish the CORF plan of treatment when referring patients to the CORF. If the referring physician has not established a plan of treatment, a facility physician is responsible for establishing a plan of treatment.

CORF physician services are administrative in nature:consultation with and medical supervision of non-physician staff, establishment and review of the plan of treatment, and other medical and facility administration activities. **Diagnostic and therapeutic services are not CORF physician services.**

(§410.100 clearly defines the types of services the professional staff may provide in a CORF).

I-534

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A facility physician need not perform emergency physician services. Rather, these services may be provided by another physician(s) or by paramedics with hospital emergency room back-up, or through other arrangements that ensures prompt delivery of emergency services. These mechanisms must be in writing, readily available and familiar to all staff. Emergency services must be available during the total operating hours of the CORF.

§485.58(b) Standard: Plan of treatment

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

For each patient, a physician must establish a plan of treatment before the facility initiates treatment. The plan of treatment must meet the following requirements:

- (1) It must delineate anticipated goals and specify the type, amount, frequency and duration of services to be provided and indicates the diagnosis and anticipated rehabilitation goals;*
- (2) It must be promptly evaluated after changes in the patient's condition and revised when necessary;*
- (3) It must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel;*
- (4) It must be reviewed at least every 60 days (the 60 day period begins with the first day of skilled rehabilitation therapy) by a facility physician who, when*

appropriate, consults with the professional personnel providing services. The results of this review must be communicated to the patient's referring physician for concurrence before treatment is continued or discontinued; and

- (5) *It must be revised if the comprehensive reassessment of the patient's condition indicates the need for revision.*

I-535, I-536, I-538

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Every patient must have a plan of treatment established, either by the facility physician, the referring physician or both in collaboration ***prior to the facility commencing treatment.*** Usually, a plan of treatment is written; however, it is acceptable in certain circumstances for a verbal order and plan to be telephoned to the CORF by the referring physician. The time, date, referring physician's name and contents of the verbal order must be documented and signed by the person receiving the order, and countersigned by the referring physician as soon as possible. Specific information relative to ***type, amount, frequency and duration of services as well as anticipated goals, should routinely be incorporated with the physician referral.*** The plan of treatment must include all of the services needed by the patient that meet the definition of CORF services. (CORF services are: physician; physical therapy; occupational therapy; speech-language pathology; respiratory; prosthetic; orthotic; social; psychological; nursing; drugs and biologicals; and supplies, appliances and equipment). For example, if a patient is in need of social services, physical therapy and speech-language pathology, all three services must be included in the CORF plan of treatment. ***The plan of treatment must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel.***

I-537, I-540

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

After treatment has begun, any change in the plan of treatment should be supported in the patient's clinical record by dated documentation signed by either the facility physician or by the referring physician. Any change in the patient's condition must be accompanied by a ***revised plan of treatment.***

A facility physician must perform a 60 day review of the plan of treatment to ***determine if the plan is being followed and whether or not the patient is making progress in attaining the established goals.*** However, the referring physician should always be given the opportunity to have continued input into the patient's treatment program.

I-539

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

In this regard, CORF staff must communicate either verbally or in writing the results of the 60-day review to the referring physician. Verbal communication should be by either a facility physician or one of the professional personnel carrying out the plan of treatment. The referring physician's verbal concurrence for revision of the plan of treatment should be documented in the patient's clinical record by the individual communicating with the referring physician. This documentation should include the date and the subject matter discussed. The referring physician's response should be incorporated into the patient's clinical record

§485.58(c) Standard: Coordination of Services

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must designate, in writing, a qualified professional to ensure that professional personnel coordinate their related activities and exchange information about each patient under their care. Mechanisms to assist in the coordination of services must include:

- (1) Providing to all personnel associated with the facility, a schedule indicating the frequency and type of services provided at the facility;*
- (2) A procedure for communicating to all patient care personnel pertinent information concerning significant changes in the patient's status;*
- (3) Periodic clinical record entries, noting at least the patient's status in relationship to goal attainment; and*
- (4) Scheduling patient case review conferences for purposes of determining appropriateness of treatment, when indicated by the results of the initial comprehensive patient assessment, reassessment(s), the recommendation of the facility physician (or other physician who established the plan of treatment), or upon recommendation of one of the professionals providing services.*

Patients receive maximum benefit from an *individualized* comprehensive, *coordinated, skilled* rehabilitation outpatient program when services are provided in a coordinated manner. In most CORFs, a multi-disciplinary team of professional personnel provides several rehabilitation services to patients. The team may include full-time and part-time employees as well as *contract* employees functioning on either a full-time or part-time basis. It is, therefore, important that the facility take steps to assure that services are provided in an efficient, effective and coordinated manner. The facility must designate in writing one professional to oversee the coordination *of CORF services* that the facility has developed. This responsibility can be performed concurrently with the assigned person's normal professional duties. *All personnel providing services at the CORF should receive a schedule of the frequency and type of services provided at the CORF.*

I-541, I-542

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review CORF policies/procedures to ensure the CORF provides in-service education regarding the importance of coordinating patient services. Evidence may also appear in the medical record in assessments, progress notes, interdisciplinary treatment team meetings, discharge planning meetings, etc. Verify that the individual identified as the coordinator is qualified to perform this function.

I-543, I-544

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Frequency of clinical record entries may range from a brief entry in a patient's clinical record each day the patient receives treatment, to entries of longer intervals. The facility must establish some procedure detailing the frequency of clinical record documentation. Since this documentation may be used as one of the factors in determining the outcome of the 60-day plan of treatment review, entries should appear frequently enough during each 60-day period to provide an adequate picture of *coordination of the* care being given and the patient's status relative to established goals.

The frequency, format, and criteria for patient case review conferences may vary among facilities. These conferences generally will be convened to determine the appropriateness of continuing treatment, changing a plan of treatment, or to coordinate treatment activities. Conferences may routinely be scheduled for each patient after the patient has been undergoing treatment for a specified period of time or has had a specified number of treatments; or conferences may be scheduled only for patients who are not meeting anticipated goals, who need a different level of care, or who are receiving an intensive multi-service rehabilitation program. There must be a written policy regarding patient case review conferences, and it should be adhered to. There should be a formal procedure to familiarize all personnel treating the patient with the results of the CORF's coordination of service activity.

I-545

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review past patient case review conference documentation and interview personnel regarding its utilization. In reviewing case conference documentation, look for evidence that the CORF has the three “core” services available.

§485.58(d) Standard: Provision of Services

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

(1) All patients must be referred to the facility by a physician who provides the following information to the facility before treatment is initiated:

(i) The patient's significant medical history;

(ii) Current medical findings;

(ii) Diagnosis(es) and contraindications to any treatment modality;

(iv) Rehabilitation goals, if determined.

(2) Services may be provided by facility employees or by others under arrangements made by the facility;

(3) The facility must have on its premises the necessary equipment to implement the plan of treatment and sufficient space to allow adequate care;

(4) The services must be furnished by personnel that meet the qualifications of § 485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in § 485.70 may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified individual must be on the premises, and must instruct these personnel in appropriate patient care service techniques and retain responsibility for their activities;

(5) A qualified professional must initiate and coordinate the appropriate portions of the plan of treatment, monitor the patient's progress, and recommend changes in the plan, if necessary;

(6) A qualified professional representing each service made available at the facility must be either on the premises of the facility or must be available through direct telecommunication for consultation and assistance during the facility's operating hours. At least one qualified professional must be on the premises during the facility's operating hours; and

(7) All services must be provided consistent with accepted professional standards and practice.

All CORF patients must be referred by a physician. The referral should contain the patient's medical history, current medical findings, diagnosis, contraindications to any treatment modality and rehabilitation goals, if determined. Current medical findings and a complete

and appropriate medical history do not always accompany a physician's referral. In such cases, a qualified professional or a facility physician should obtain this information from the patient and obtain additional necessary information through follow-up with the referring physician.

I-546

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review medical records to ensure the CORF patients have a referral and the information listed above.

CORF services may be provided by employees or by others under arrangements, i.e., individuals from an organization that has a contract with the facility to provide services, and individuals that contract directly with the CORF. A CORF need not expressly employ professional personnel under an arrangement exclusively for a CORF. Personnel may be associated with other organizations while they are associated with the CORF, but must be available during operating hours. For example, a principal(s) of a skilled nursing facility (SNF) may also own a CORF and share personnel between these two providers. This is permissible and satisfies compliance with regulations when these personnel are able to **perform** exclusively for each provider, **respectively**, in carrying out **specific** responsibilities. This is especially important because each CORF is a separate identifiable provider and must independently meet the conditions of participation.

I-529, I-531, I-547

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review contracts the CORF has for providing services under arrangement. The CORF has the administrative responsibility for the services provided to its patient.

I-548

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Ascertain that the CORF has the equipment and personnel necessary to adequately and effectively provide the services ***as defined in the plan of treatment***. Review medical records to determine specific equipment requirements from the plans of treatment, and verify the presence of such equipment.

I-548

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A facility need not own all of the equipment required for implementing the plan of treatment. It is permissible to rent or lease necessary equipment on an as needed basis. ***The CORF***

must demonstrate that all required equipment will be readily procured, obtained and available on the premises when providing treatment services to the patients. The CORF cannot share equipment with any other entity during its hours of operation. Ensure equipment levels are sufficient to treat patients.

I-549

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Adequacy of staffing levels of qualified professionals and other staff should be based upon the types of patients treated and the frequency, duration and complexity of treatment required, rather than general staff to patient ratios.

I-549

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

When *non-professional* personnel other than those that are noted in the personnel qualification section of the conditions of participation (see §485.70) are used to assist qualified professionals, their duties, responsibilities and qualifications should appear in the facility's policies and be consistent with accepted standards and practices. Appropriately qualified personnel must instruct all *non-professional* personnel in specific patient care techniques.

I-549

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The form and extent of any instruction provided to non-professional personnel must be appropriate to that person's assigned responsibilities, education, experience and types of patients treated. The appropriately qualified professional must be on the premises, and supervise the care given when non-professional personnel are utilized. Verify this through a review of the treatment and staffing schedule. For example, when non-professional personnel are used in conjunction with the furnishing of physical therapy services, a person meeting the qualification requirements of §485.70 (formerly §488.70) must be on the premises.

Qualified professional personnel may initiate changes that need to be made concerning the implementation of the plan of treatment. Assistant-level personnel (as defined in §485.70 and §484.4) must not initiate such changes without the approval of the appropriately qualified professional.. *Qualified personnel must be available for duty on the CORF's premises as **needed for consultation and/or assistance** or must be able to be contacted by telephone.*

I-550

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Consultation and assistance cannot be provided to non-professional personnel by phone as they require on the premises supervision.

I-551

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

At least one qualified professional must be on the facility's premises during its hours of operation.

It may not be unusual to find that, in a CORF that furnishes a broad array of rehabilitation services, several types of professionals are furnishing particular aspects of care. For example, registered nurses with special training in respiratory care or physical therapists may furnish respiratory therapy services.

The CORF is responsible for ensuring that a practitioner furnishing a particular service is qualified to do so under State law and does so within accepted professional standards and practices. Carefully review the qualifications of a professional providing more than one CORF service. Determine the scope of the particular service.

I-552

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Verify that the practitioner is qualified to provide the service, and that it is provided pursuant to State law and accepted professional standards and practices.

§485.58(e) Standard: Scope and Site of Services

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

(1) Basic requirements: the facility must provide all the CORF services required in the plan of treatment and, except as provided in paragraph (e)(2) of this section, must provide the services on its premises;

(2) Exceptions: physical therapy, occupational therapy and speech pathology services furnished away from the premises of the CORF may be covered as CORF services if Medicare payment is not otherwise made for these services. In addition, a single home

visit is covered if there is need to evaluate the potential impact of the home environment on the rehabilitation goals. The home evaluation is not covered as a routine service for all CORF patients. It is covered only if, in establishing or carrying out the plan of treatment, there is a clear indication that the home environment might adversely affect the patient's rehabilitation. Coverage is limited to the services of one professional either physical or occupational therapist, (whose services are covered by the CORF benefit) who is selected by the CORF.

In general, all services must be furnished on the premises of the CORF. The only exceptions are the home evaluation visit. The provision allowing offsite therapy services does not permit the CORF to establish extension locations and all records must be maintained on the premises of the CORF. The purpose of the home visit is to evaluate the home environment in relation to the patient's established treatment goals. The home visit evaluation may include assessing the need for modifying the physical and/or social environment to maximize the patient's functional capability. The home, for purposes of this home evaluation visit, is the patient's legal residence. The visit may take place anytime between the implementation of the plan of treatment and the discharge of the patient. A patient who is periodically discharged and admitted for a chronic but stable problem would not normally receive more than one home evaluation visit, even though the patient may be receiving more than one service.

I-553

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

*Ask the CORF if therapy services are provided off-site and if so, which services are provided. Even though the CORF patients can be treated in off-site locations by therapists, the CORF is ultimately responsible for the coordinated, comprehensive rehabilitation program for each patient. All appropriate CoPs apply to the services provided at off-site locations.
Review clinical records.*

Notes in the patient's clinical record should indicate when the visit was made, who made it, its purpose and the results of the evaluation.

Also, the CORF must provide all the CORF services required in the plan of treatment. Since personnel may provide these services under arrangements, there should be minimal difficulty in obtaining personnel to provide services regardless of the infrequency of demand for the service. The unavailability of a service forces the patient to seek the service at another location. This is contrary to one of the purposes of the CORF legislation, i.e., to remedy the situation where beneficiaries needing several rehabilitation services are required to seek them at more than one location.

NOTE: When completing the CORF Survey Report Form (CMS-360) do not mark standard 485.58(e) (tag number 1-553) "no" if the CORF provides physical

therapy, occupational therapy or speech pathology services offsite. We will revise the CMS-360 to include this offsite provision when it is reprinted.

§485.58(f) Standard: Patient Assessment

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Each qualified professional involved in the patient's care, as specified in the plan of treatment, must—(1) carry out an initial patient assessment; and (2) In order to identify whether or not the current plan of treatment is appropriate, perform a patient reassessment after significant changes in the patient's status.

Each qualified individual, providing services to a patient, must conduct an initial patient assessment with periodic reassessment of the patient to determine whether the patient is meeting rehabilitation goals and to update the plan of treatment. Because the reassessment usually consists of the same evaluative mechanisms (e.g., test procedures, measurements, professional observations and subjective information from patient) used in the initial assessment to obtain indicators of the patient's status, the patient's status at different points in time can be compared. Since a reassessment must be performed when significant changes in the patient's condition are noted, such a comparison is useful to determine whether the current plan of treatment is appropriate. In contrast to the information obtained in a reassessment, periodic entries in the clinical record as required in §485.58(c)(3) usually contain information such as a patient's reaction to treatment, general condition of patient, significant changes in patient's status and/or changes in the intensity of treatment. These entries provide in chronological order a picture of the patient's progress in relation to the care being given.

Verify that each patient is assessed by each qualified professional personnel involved in the patient's care prior to the implementation of the plan of treatment. *During a review of the clinical records compare the date the plan of treatment was established to the date of the initial assessment by the appropriate professional defined in §485.70. If the plan of treatment specifies several rehabilitation services, the professional personnel responsible for initiating the plan may be unable to complete their respective assessments on the same day. For example, the physical therapist may complete an assessment of the patient and initiate the physical therapy service portion of the plan before the speech pathologist assesses the patient. However, if the physician ordered all therapies to assess and begin treatment upon receipt of the plan of care, it is reasonable to expect all assessments be completed in the first week of receiving the plan of treatment.*

I-554, I-555, I-556

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the clinical records for availability of an initial assessment and re-assessments as

appropriate

§485.58(g) Standard: Laboratory services

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

- (1) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter;*
- (2) If the facility chooses to refer specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of Part 493 of this chapter.*

A CORF may either conduct its own laboratory services or refer specimens to another laboratory. Either laboratory must meet the applicable requirements at 42 CFR §493. The laboratory must meet any and all State requirements for certification or licensure.

I-557, I-558

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review certification/licensure if the CORF offers laboratory services.

42 CFR 485.60 *Condition of Participation: Clinical Records*

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must maintain clinical records on all patients in accordance with accepted professional standards and practice. The clinical records must be completely, promptly, systematically organized to facilitate retrieval and compilation of information.

A - General

The clinical record serves as a basis for documentation of care rendered to the patient and communication between all personnel furnishing services. Determine whether the content of the clinical record presents a total, or at a minimum, an adequate picture of the care being given.

B - Major Sources of Information

- Active and closed clinical records; and
- Policies regarding protection and retention of clinical records.

C - Standards

§485.60(a) Standard: Content

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Each clinical record must contain sufficient information to identify the patient clearly and to justify the diagnosis and treatment. Entries in the clinical record must be made as frequently as is necessary to insure effective treatment, and must be signed by personnel providing services. All entries made by assistant level personnel must be countersigned by the corresponding professional. Documentation on each patient must be consolidated into one clinical record that must contain:

- (1) The initial assessment and subsequent reassessments of the patient's needs;*
- (2) Current plan of treatment;*
- (3) Identification data and consent or authorization forms;*
- (4) Pertinent medical history, past and present;*
- (5) A report of pertinent physical examinations if any;*
- (6) Progress notes or other documentation that reflect patient reaction to treatment, tests, or injury, or the need to change the established plan of treatment; and*
- (7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis, and future treatment considerations.*

All medical records must be maintained according to accepted professional standards of practice. The medical records must be readily available to staff and surveyors.

I-559

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Examine a substantial number of both active and closed clinical records and ascertain that the required material is included. If any of the material required in this standard (§485.60(a)) is absent from the clinical records, review additional records to determine the prevalence of such omissions. Record the number of records reviewed and the number and types of deficiencies observed. In determining the number of records to be reviewed, be guided by the size of the CORF's patient caseload. The larger the caseload, the larger the review sample should be.

Each patient's record should contain a summary of each patient's case review conference,

where appropriate, and indicate the purpose and recommendation resulting from the conference. All reports generated as a result of any meetings concerning patient care issues should be dated, signed and made a part of the record.

I-566

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Ascertain that periodic progress notes are entered in the clinical records at intervals commensurate with the type and frequency of treatment. These notes are to address the progress of the patient in attaining stated plan of treatment goals. Some facilities may require a brief entry in the clinical record each day the patient receives a treatment while other facilities may require routine progress reports at longer intervals. Ascertain the time interval between progress reports. Determine whether the time interval is impeding coordination and communication in patient care activities. Regardless of the frequency of progress notes, the notes should record the patient's status in relation to the stated treatment goals.

I-567

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A discharge summary should include the date and reason for discharge, a brief summary of the patient's current status and, where applicable, details regarding referral of the patient to another level of care.

I-560, I-567

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

All information appearing in the clinical record must be dated, appropriately signed and promptly incorporated in the record. *Regulations require that entries written by therapy assistants be countersigned even though some state practice acts may not require this. All entries in the clinical record must be legible.*

A physician must certify that CORF services are required because the individual needs skilled rehabilitation services. The treatment plan must include a diagnosis and must address rehabilitation goals associated with that particular diagnosis. Throughout the course of rehabilitation treatment, the medical records must indicate the ongoing services provided by a physical therapist, social worker or psychologist.

Verify the medical records contain signed and dated certifications and re-certifications.

§485.60(b) Standard: Protection of Clinical Record Information

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must safeguard clinical record information against loss, destruction, or unauthorized use. The facility must have procedures that govern the use and removal of records and the conditions for release of information. The facility must obtain the patient's written consent before releasing information not required by law.

Verify that active and closed clinical records are stored where they are protected from fire and unauthorized use.

I-568, I-569

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the CORFs written procedures governing the use of records which specify to whom the records or copies of records may be provided, the use to which the material may be put and the circumstances describing the return of such material. Also, review the medical records to determine that written patient consent is present to allow the release of all material not authorized by law.

§485.60(c) Standard: Retention and Preservation

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must retain clinical record information for 5 years after patient discharge and must make provision for the maintenance of such records in the event that it is no longer able to treat patients.

The facility must provide for the maintenance of clinical records in cases where the CORF ceases to function.

I-569

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the CORF's policy for the preservation and retention of clinical records and verify that applicable State laws or regulations are met.

42 CFR 485.62 *Condition of Participation* - Physical Environment

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must provide a physical environment that protects the health and safety of patients, personnel, and the public.

A - General

I-570

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A CORF must provide a physical environment that protects the health and safety of the staff, patients and public.

B - Major Sources of Information

1. Applicable State and local laws;
2. Inspection reports of State and local building and fire authorities; and
3. Organization policies and procedures regarding maintenance of equipment, buildings and grounds.

C - Standards

485.62(a) Standard: Safety and Comfort of Patients

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The physical premises of the facility and those areas of its surrounding physical structure that are used by the patients (including at least all stairwells, corridors and passageways) must meet the following requirements:

- (1) Applicable Federal, State, and local building, fire and safety codes must be met;*
- (2) Fire extinguishers must be easily accessible and fire regulations must be prominently posted;*
- (3) A fire alarm system with local (in-house) capability must be functional, and where power is generated by electricity, an alternate power source, with automatic triggering must be present;*
- (4) Lights, supported by an emergency power source, must be placed at exits;*
- (5) A sufficient number of staff to evacuate patients during a disaster must be on the premises of the facility whenever patients are being treated;*

(6) Lighting must be sufficient to carry out services safely; room temperature must be maintained at comfortable levels; and ventilation through windows, mechanical means, or a combination of both must be provided; and

(7) Safe and sufficient space must be available for the scope of services offered.

I-572

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review available reports of State and local personnel responsible for enforcement of building, fire and safety codes and verify that the CORF is in compliance with applicable codes.

All areas occupied or accessible to the facility for use during emergency or non-emergency activity, including corridors and stairways, are to be protected by easily accessible fire extinguishers. Lights, supported by an emergency power source, must be placed at exits. **Where there is a CORF established on the premises of another health entity, also survey those areas which are common to both, i.e., corridors, stairways, storage areas, etc.**

The fire alarm system must be adequate to alert personnel in time for safe evacuation of the building. The system should consist of either a manual (pull type) fire alarm system with or without automatic fire department response, or an automatic detection system along with an audible manual alarm. Any system should have the capacity for manual activation that triggers an audible in-house alarm which alerts personnel, patients and the public to the present danger and need for action. Where the alarm system is activated by a disruption of the electrical system or in other ways dependent on it, an emergency power source with automatic triggering, e.g., battery or auxiliary generator, must be available to serve as a backup. In the absence of State or local requirements, the above systems are to be approved by the State Fire Marshall's Office.

I-573 and I-574

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)
Verify the availability of fire extinguishers and fire alarms.

The number of staff necessary to evacuate patients during an emergency depends largely on the number and types of patients scheduled to be on the premises at any one time. A patient population consisting largely of patients dependent on assistive devices for ambulating (e.g., canes, crutches and walkers), wheelchair bound patients and other patients who would need assistance from CORF personnel for a quick, safe evacuation, would require the presence of more staff than a patient population which is not dependent on ambulatory assistive devices.

I-576

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Observe the number of staff and the types of patients to determine the efficiency of an evacuation in case of an emergency.

An emergency power source must be supplied, e.g., by battery or auxiliary generator, to assure adequate lighting during emergency operation within the treatment areas or those passageways, stairwells and exits (as noted above) accessible to the CORF. In cases of power outage, the emergency power source should respond either automatically or require only minimal activation effort.

I-577 and I-578

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Verify that the temperature and ventilation is maintained at a comfortable level.

§485.62(b) Standard: Sanitary Environment

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent, and control the cause of patient infections:

- (1) The facility must establish written policies and procedures designed to control and prevent infection in the facility and to investigate and identify possible causes of infection;***
- (2) The facility must monitor the infection control program to ensure that the staff implement the policies and procedures and that the policies and procedures are consistent with current practices in the field;***
- (3) The facility must make available at all times a quantity of laundered linen adequate for proper care and comfort of patients. Linens must be handled, stored, and processed in a manner that prevents the spread of infection; and***
- (4) Provisions must be in effect that the facility's premises are maintained free of rodent and insect infestation.***

I-579

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

***Verify that* the facility maintains a sanitary environment and has established a program to identify, investigate, prevent and control the cause of patient infections.**

I-580

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the written policies and procedures regarding infection control and maintenance of a sanitary environment.

Verify that they are sufficient in light of the volume and types of patients and services provided, and that there is consistency with current practices of infection control.

Identify the individual or group responsible for establishing, implementing and monitoring the policies and procedures. The facility must monitor the infection control program to ensure that policies and procedures are being complied with and are consistent with currently accepted practices, if applicable. Pay particular attention to the policies, procedures and reports concerning the care and debridement of wounds, and the cleaning and disinfection of equipment such as whirlpools and paraffin baths and respiratory therapy equipment.

Verify the general sanitation, cleanliness and orderliness of the premises and verify that clean and soiled linen is handled in an orderly and sanitary manner that will prevent the spread of infection. There must be an adequate supply of fresh linen (sheets, towels, pillowcases) which must be stored and processed separate from soiled linen. Soiled linen must be processed and stored in an area away from patients, personnel and the public.

I-579 – I-583

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the CORF policies and procedures regarding preventive maintenance and infection control to determine if they are compatible with the scope of services, the type of equipment used and type of patients accepted for treatment.

§485.62(c) Standard: Maintenance of Equipment, Physical Location and Grounds

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must establish a written preventive maintenance program to ensure that:

- (1) All equipment is properly maintained and equipment needing periodic calibration is calibrated consistent with the manufacturer's recommendations;***

and

(2) The interior of the facility, the exterior of the physical structure housing the facility, and the exterior walkways and parking areas are clean and orderly and maintained free of any defects that are a hazard to patients, personnel, and the public.

CORF personnel should inspect all equipment *as per the manufacturer's directions* or more frequently depending on equipment condition and its frequency of use. Written procedures regarding the preventive maintenance program must include the following: equipment to be inspected, a brief statement concerning the general inspection process and frequency of inspection for each piece of equipment. For all electrically powered patient care equipment, appropriate manufacturer's operating and maintenance information must be on file.

I-584—I-585

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review this information and ascertain what specific manufacturer's recommendations, if any, are made for equipment calibration checks, periodic maintenance procedures, etc. Then, through copies of service repair statements or other documentation, determine whether such recommendations were followed.

I-586

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must be free of hazards to the health and safety of patients, personnel and the public, e.g., broken window and door panes, obstruction of passageways and dangerous floor surfaces, and any hazardous exterior walkways or parking areas. Hazards are to be brought to the attention of CORF personnel.

§485.62(d) Standard: Access for the Physically Impaired

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must ensure the following:

(1) Doorways, stairwells, corridors, and passageways used by patients are:

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs); and

- (ii) In the case of stairwells, equipped with firmly attached handrails on at least one side.*
- (2) At least one toilet facility is accessible and constructed to allow utilization by ambulatory and non-ambulatory individuals;*
- (3) At least one entrance is usable by individuals in wheelchairs;*
- (4) In multi-story buildings, elevators are accessible to and usable by the physically impaired on the level that they use to enter the building and all levels normally used by the patients of the facility;*
- (5) Parking spaces are large enough and close enough to the facility to allow safe access by the physically impaired.*

The CORF must ensure the exits and entrances are wide enough to allow for easy movement of all patients whether they are ambulatory, in a wheelchair or on a stretcher and that the exits and entrances are not blocked with furniture or equipment. For patients who use a stairwell, rails must be firmly attached on one wall. A wheelchair entrance must be equipped with a suitable ramp if needed.

I-587 - I-592

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Inspect the premises to verify whether the facility ensures safe access and adequate space to maneuver in waiting areas, treatment areas and toilet facilities for all physically impaired patients including those on stretchers or in wheelchairs. *Verify that at least one toilet facility can be used by ambulatory and nonambulatory patients, that is, grab bars are provided, elevated toilets seats are available, etc. If the CORF is in a multi-story building at least one elevator is available and functioning for the physically impaired who are entering or leaving the premises as well as to all patient areas that are part of the CORF.*

(42 CFR 485.64) *Condition of Participation: Disaster Procedures*

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. All personnel associated with the facility must be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

A - General

A well-developed disaster plan is to be documented and posted in areas accessible for

continuing personnel review and where the public can see it.

B - Major Sources of Information

- Disaster plan; and
- Documentation as to ongoing training sessions and dates of disaster drills

C - Standards

§485.64(a) Standard: Disaster Plan

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility's written disaster plan must be developed and maintained with assistance of qualified fire, safety, and other appropriate experts. The plan must include:

- (1) Procedures for prompt transfer of casualties and records;*
- (2) Procedures for notifying community emergency personnel (for example, fire department, ambulance, etc.);*
- (3) Instructions regarding the location and use of alarm systems and signals and fire fighting equipment; and*
- (4) Specification of evacuation routes and procedures for leaving the facility.*

The disaster plan should document the assignment of responsibilities to CORF personnel providing services to the CORF, evacuation routes, and procedures for the transfer of records and casualties. In addition, the plan should include procedures for notifying community emergency personnel, procedures for leaving the facility and instructions regarding the location and use of alarms and fire fighting equipment.

I-594 - I-598

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the disaster plan to determine if the plan documents all of the above procedures and instructions. *If CORF employees are working at off-site locations, it is incumbent upon the CORF to ensure those employees have been trained and are knowledgeable regarding disaster plans, evacuation routes for those locations, etc. Surveyors should interview staff to determine whether the CORF has provided training in the off-site locations.*

§485.64(b) Standard: Drills and Staff Training

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

(1) The facility must provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness; and

(2) All new personnel must be oriented and assigned specific responsibilities regarding the facility's disaster plan within 2 weeks of their first workday.

Every CORF must provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness. Larger, more complex CORFs would most likely provide ongoing training more frequently than smaller CORFs. All new employees must be oriented and assigned specific responsibilities as part of the disaster plan within 2 weeks of their first workday. This includes all employees who provide services to the CORF under an arrangement. The date of training and names of those persons taking part are to be documented.

I-600 - I-601

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Review the CORF's written Disaster Plan. Verify that all personnel have been instructed and trained in their responsibilities and that all new personnel are properly trained within 2 weeks of their first workday. Interview the staff to ensure that they are familiar with the plan as well as being familiar with their role in the plan.

42 CFR 485.66 Condition of Participation: Utilization Review Plan

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The facility must have in effect a written utilization review plan that is implemented at least each quarter, to assess the necessity of services and promotes the most efficient use of services provide by the facility.

A - General

(I-602) Each facility must have in effect, a written utilization review plan. An established utilization review plan serves to indicate how well policies are functioning, how effective treatment regimens have been, and how well the CORF has adapted its particular program to selected patients.

B - Major Sources of Information

- Clinical records; and
- Written utilization plan

C - Standards

§485.66(a) Standard: Utilization Review Committee

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The utilization review committee, consisting of the group of professional personnel specified in §485.56(c), a committee of this group, or a group of similar composition, comprised by professional personnel not associated with the facility must carry out the utilization review plan.

I-603

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The Utilization Review (UR) Committee must meet at least quarterly. *The composition of this committee should be written into the utilization review plan and should be representative of the professional personnel that provide services in the CORF. A facility physician or non-CORF physician must be a member of the UR committee.*

§485.66(b) Standard: Utilization Review Plan

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The utilization review plan must contain written procedures for evaluating:

- (1) Admissions, continued care, and discharges using, at a minimum, the criteria established in the patient care policies;*
- (2) The applicability of the plan of treatment to established goals; and*
- (3) The adequacy of clinical records with regard to:*
 - (i) Assessing the quality of services provided;*
 - (ii) Determining whether the facility's policies and clinical practices are compatible and promote appropriate and efficient utilization of services.*

The plan should contain specific procedures and standards necessary to assess the effectiveness and efficiency of the services provided. The number of cases selected for review should be representative of the types of patients treated at the CORF and the types of

services provided. The frequency of reviews should be outlined in the plan.

Reports and outcomes of evaluations should be reflected in the minutes of the utilization review committee. Those minutes should also indicate the extent to which the CORF program, policies and practices are being followed. *Review the minutes of the utilization review committee to determine if the plan is being followed.*

I-604 - I-607

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Results of utilization review activities should be made available to all professional personnel. **Identify whether the results of the review prompted recommendations concerning CORF policies and practices and whether the recommendations were communicated to the administrator and governing body and the group of professional personnel (if different from the utilization review committee).**

GENERAL COMMENTS:

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A CORF may be established on the premises of another health entity irrespective of whether this entity is already certified under Medicare as a provider or supplier of services. For example, a CORF may be established on the premises of a skilled nursing facility (SNF) and the SNF's owner(s) may either have legal responsibility for both the SNF and the CORF, or merely rent space within the SNF to the CORF's owner(s). In either situation, the CORF must be certified separately and be functionally and operationally independent. The regulatory definition of a CORF precludes the CORF, and another entity from mixing functions and operations in a common space during concurrent or overlapping hours of operation.

In the same manner as space may be shared, equipment may also be shared. All common equipment must be available (on the premises of the CORF) during the CORF's hours of operation and not, at that time, be utilized by the other entity for any purpose.

The CORFs must be surveyed pursuant to the CORF conditions of participation and all standards must be surveyed independent of any findings resulting from the completed survey of the other entity. That is, although there may have been no deficiencies noted during the survey of the other entity, this fact must not influence any determination with respect to the survey pursuant to the CORF conditions of participation.